87-1151

No.———

IN THE

Supreme Court of the United States

OCTOBER TERM, 1987

LEDERLE LABORATORIES, a division of
American Cyanamid Company,
Petitioner

v.

DAVID TONER, *et al.*,
Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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QUESTION PRESENTED

Whether the Court of Appeals, in attempting to reconcile two inconsistent special verdicts by a unifying interpretation that was "not beyond peradventure," misapplied this Court's requirement that inconsistent verdicts be reconciled only when justified by a "fair reading" of them, thereby creating a conflict with decisions of two other circuits that have held these same inconsistencies to be irreconcilable.

STATEMENT UNDER RULE 28.1

Pursuant to Supreme Court Rule 28.1, Petitioner Lederle Laboratories states that Lederle Laboratories is a division of American Cyanamid Company.

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OPINIONS BELOW

The opinion of the court of appeals below is reported at 828 F.2d 510 (9th Cir. 1987). *See* Appendix A. An earlier opinion of the court of appeals, certifying questions to the Idaho Supreme Court, is reported at 779 F.2d 1429 (9th Cir. 1986). *See* Appendix B. The Idaho Supreme Court's response to the certified questions is reported at 732 P.2d 297. *See* Appendix C.

JURISDICTION

The decision of the court of appeals was entered on September 16, 1987. On November 23, 1987, a timely petition for rehearing was denied and a suggestion for rehearing *en banc* was rejected. *See* Appendix D. This

Court's jurisdiction to review the judgment below by writ of certiorari is conferred by 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves the Seventh Amendment's provision that "In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved . . . ." It also involves the following provision of Rule 49(a) of the Federal Rules of Civil Procedure:

> Special Verdicts. The court may require a jury to return only a special verdict in the form of a special written finding upon each issue of fact. In that event the court may submit to the jury written questions susceptible of categorical or other brief answer or may submit written forms of the several special findings which might properly be made under the pleadings and evidence; or it may use such other method of submitting the issues and requiring the written findings thereon as it deems most appropriate. The court shall give to the jury such explanation and instruction concerning the matter thus submitted as may be necessary to enable the jury to make its findings upon each issue.

STATEMENT

Respondent Kevin Toner suffers from transverse myelitis, a paralytic disorder. He claims his injury was caused by an injection of Tri-Immunol®, a whole-cell diphtheria, tetanus, and pertussis ("DTP") vaccine manufactured by petitioner Lederle Laboratories ("Lederle"). Respondents filed suit against petitioner in Idaho state court and petitioner removed the case to federal court on the basis of diversity of citizenship under 28 U.S.C. § 1441. Respondents' complaint alleged that Lederle was liable for Kevin Toner's injuries on three theories: strict liability, negligence, and breach of warranty of mer-

chantability. Initially, respondents' complaint charged that Lederle was negligent both in failing to provide adequate warnings and in designing Tri-Immunol. Respondents, however, withdrew their warning claims before the case was submitted to the jury. *See Toner v. Lederle Laboratories*, 779 F.2d at 1430, Appendix B at 11a. With the withdrawal of the warning claim, respondents' remaining claims all centered on the theory that Lederle was at fault for manufacturing a DTP vaccine of a whole-cell design rather than a vaccine of an allegedly safer "fractionated-cell" design.[1]

During a ten day trial in Idaho federal court, respondents relied on identical evidence to establish both the strict liability claim that Tri-Immunol was unreasonably dangerous and the claim that it was negligent for Lederle to sell a whole-cell vaccine like Tri-Immunol when there allegedly were alternative designs that were safer and no less effective. That evidence consisted primarily of testimony, vigorously contested by petitioner's witnesses, (1) that whole-cell vaccines like Tri-Immunol posed a greater risk of severe reactions than Tri-Solgen®,[2] a fractionated, non-whole-cell type once made by Eli Lilly, (2) that a fractionated Tri-Solgen-type vaccine could have been developed and marketed by Lederle,[3] and (3) that

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[1] No vaccine can be sold unless licensed by the United States Government as safe and effective. Whole-cell pertussis vaccine is the only pertussis vaccine now so licensed. No fractionated-cell vaccine is now licensed as safe and effective, and in *amicus* briefs filed in several recent vaccine liability cases, the United States is on record that fractionated-cell vaccines and other alternative pertussis vaccines "have not yet been adequately shown to be safe and effective for licensure in the United States." *See* Brief for the United States as *Amicus Curiae*, filed on behalf of the Department of Health and Human Services in *Abbot v. American Cyanamid Co.*, No. 87-1578 (4th Cir.) (filed August 24, 1987) at 16 (hereinafter "HHS *Amicus* Brief"). The brief is reprinted in Appendix E.

[2] *See, e.g.*, Tr. 46 (April 11, 1984) (Testimony of Respondents' expert Robert Waldman).

[3] *See, e.g.*, Tr. 53, Vol. V (Testimony of Respondents' expert Robert Laird).

such an alternative vaccine would have been safer than Tri-Immunol and equally effective in conferring immunity to pertussis.[4]

In their closing argument, respondents emphasized that the evidence showed negligence because Lederle breached its duty to make a vaccine "as safe as they can and . . . not to subject children to unnecessary risk."[5] The same evidence—that Tri-Immunol was "knowingly more toxic than it has to be reasonably speaking"—was invoked by respondents to argue that whole-cell vaccines like Tri-Immunol were defective and unreasonably dangerous, thus giving rise to strict liability for any injury they caused.[6]

On April 23, 1984, the district court submitted the case to the jury. In instructing the jury, the court characterized respondents' strict liability claim as a claim that "at the time the vaccine was manufactured it was defective, in that it subjected the users to an unnecessary risk of serious harm or death," and explained that "a product is in a defective condition, unreasonably dangerous to persons if it is more dangerous than would be expected by an ordinary person who may reasonably be expected to use it." With respect to the negligence claim, the court instructed the jury that "[t]he manufacturer of a product is negligent if he does not use ordinary care in the design or manufacture of that product to avoid an unreasonable risk of forseeable injury to a person using the product with ordinary care. *See* Appendix F at 104a.

Finally, the court, employing Rule 49(a) of the Federal Rules of Civil Procedure, instructed the jury to render five special verdicts. In response to the court's special interrogatories, the jury determined (1) that Lederle

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[4] *See, e.g.*, Tr. 33-34 (April 11, 1984) (Testimony of Respondents' expert Robert Waldman).

[5] Tr. at 56 (April 23, 1984) (Closing Argument of Respondents' Counsel).

[6] *Id.*

was "negligent in connection with the product Tri-Immunol," (2) that Tri-Immunol was *not* manufactured "in a defective condition unreasonably dangerous to persons" and (3) that Lederle did *not* "breach an implied warranty of merchantability in connection with the product Tri-Immunol." *See* 779 F.2d at 1433, Appendix B at 18a-19a. The jury determined that the total amount of damages sustained by respondents as a result of the injury was $1,131,200. *See id.* The court entered judgment in that amount against petitioner, based on the jury's finding of negligence.

On appeal to the Court of Appeals for the Ninth Circuit, Lederle argued, among other things, (1) that the jury instructions on negligence and strict liability were deficient in that the court failed to instruct the jury to determine whether Tri-Immunol was an "unavoidably unsafe" product within the meaning of Restatement (Second) of Torts Section 402A, comment k (1965); and (2) that the jury's negligence finding was fatally inconsistent with its finding that the product was not unreasonably dangerous, and with its breach of warranty finding that Tri-Immunol was fit for its ordinary purposes. Because respondents had abandoned their "failure to warn" theory of negligence, so that the only remaining negligence issue was negligence in design, petitioners argued that the findings of "not unreasonably dangerous" and no breach of warranty could not be reconciled with a finding of negligent design.

In the absence of Idaho case law on the applicability of comment k to negligence and strict liability claims in Idaho, or the standards of care "applicable to the manufacturers of drugs that are unsafe in some respects but that are necessary for the control of disease," the court of appeals certified four questions to the Idaho Supreme Court. *See* 779 F.2d at 1432, Appendix B at 16a-18a. The court of appeals declined to reach Lederle's argument that the jury's verdict was internally inconsistent in advance of the Idaho court's decision on the certified

questions. *Id.* at 1434, Appendix B at 18a-19a. The Idaho Supreme Court accepted two of the four certified questions: the first, which asked whether the principles of comment k govern strict liability and negligence claims under Idaho law; and the fourth, which asked whether the jury instructions on negligence in this case accorded with Idaho law. *See* 828 F.2d at 511, Appendix A at 3a.

The response of the Idaho court—consisting of a complex majority opinion and three separate concurring opinions [7]—indicated that Idaho law does incorporate the principles of comment k. And while the Idaho court reasoned that "comment k immunity extends *in a literal sense* only to strict liability claims, and not to negligence claims," 732 P.2d at 305 n.6, Appendix C at 34a n.6 (emphasis added), it nonetheless recognized that comment k principles and negligence principles generally overlap with respect to the need to balance a product's risks and benefits and to consider the feasibility of alternatives. *Id.* at 310-11, Appendix C at 45a-46a. The court concluded that "the determination under comment k that the design of a product is unavoidably unsafe and yet affords benefits outweighing its risks *varies little* from the determination under negligence law that the designing and marketing of the product was reasonably done." *Id.* at 311, Appendix C at 45a (emphasis added).[8]

Petitioner then argued, in supplemental briefing in the court of appeals, that, under Idaho law, the balancing needed to determine whether "the designing and marketing of a product" is negligent because it "was [not] rea-

[7] *See Toner v. Lederle Laboratories*, 732 P.2d 297 (Idaho 1987). *See* Appendix C.

[8] Justice Bakes, in his concurring opinion, echoed and sharpened the majority's conclusion, stating that "the determination in negligence law of whether the product presents an 'unreasonable risk of harm' to the consumer *is really no different* from the determination in strict liability law that a product is 'unreasonably dangerous' to the consumer." 732 P.2d at 318, Appendix C at 60a (emphasis added).

sonably done" is the same as the balancing needed to determine whether a product is unreasonably dangerous and defective under section 402A. Petitioner argued that a finding of negligence because the designing or marketing of a product "was [not] reasonably done" could be consistent with a finding that the product was not unreasonably dangerous only if the marketing of the product was negligent because of "inadequate warning." But where, as here, there was no "failure to warn" claim, petitioner argued that a negligence finding that a product's design was not "reasonably done" could not be reconciled with a finding that the product was "not unreasonably dangerous."

The court of appeals, however, affirmed the judgment for the plaintiff. The court concluded that under Idaho law the jury instructions on negligence sufficiently incorporated an instruction on the comment k exception to strict liability [9] and that the jury's special verdicts were not inconsistent.

Although the court acknowledged the "abstract symmetry" of Lederle's argument on the inconsistency of the

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[9] Based on the Idaho court's response, the court of appeals held that

> The instruction on negligence permitted the jury to assess the reasonableness of Lederle's conduct "in light of all the attendant circumstances," *Id.* at 312, among which were the state of scientific knowledge and the utility of the Tri-Immunol vaccine in light of alternatives known by Lederle to be available. The concern we expressed in our prior opinion, that "the trial court may have omitted a material element of negligence in failing to instruct the jury to decide whether Tri-Immunol was an unavoidably unsafe product," 779 F.2d at 1432, has been allayed.

828 F.2d at 512; Appendix A at 4a-5a. The Idaho court had also expressed its view that the district court's instructions to the jury on negligence implicitly included the requisite instruction on comment k principles since, under the instruction given, "the jury undoubtedly considered the state of scientific knowledge and the utility of the vaccine before assigning negligence." 732 F.2d at 312, Appendix C at 48a.

verdicts, the court emphasized its "duty to reconcile the jury verdicts if there is a reasonable way to do so." 828 F.2d at 513, Appendix A at 6a. The court distinguished negligence claims from strict liability claims on the ground that "the focus in negligence is on the manufacturer's conduct, while in strict liability it is on the product and the user's expectations." 828 F.2d at 513, Appendix A at 6a. The court concluded that the whole-cell Tri-Immunol vaccine might be deemed reasonably safe "from the vantage point of the ordinary consumer" even though a manufacturer could still be found negligent for failing to replace it with a better product. *Id.* The court found that this way of reconciling the verdicts was fully consistent with the plaintiff's abandonment of its warning claim; it concluded that the jury could have determined that some risks that a manufacturer had a duty to eliminate would not be "expected by an ordinary person," and that the jury could reach this conclusion even in the absence of a failure to warn claim. *Id.* Reasoning from these premises, the court concluded that "[i]t is reasonable to read the special verdicts as saying that Lederle's failure to develop the [fractionated] Tri-Solgen vaccine was unreasonable conduct, although the danger posed by the [whole-cell Tri-Immunol] product itself was not greater than an ordinary consumer would reasonably expect." *Id.*

The court also attempted to reconcile the jury's negligence finding with its finding that Lederle did not breach the warranty of merchantability. The court reasoned that "[i]t is not beyond peradventure that the jury thought that Tri-Immunol was fit for the purposes for which it was to be used, but that Lederle was negligent in failing to replace it with a better product." 828 F.2d at 514, Appendix A at 8a.

REASONS FOR GRANTING THE WRIT

CERTIORARI SHOULD BE GRANTED BECAUSE THE LOWER COURT'S ENTRY OF JUDGMENT FOR THE PLAINTIFF ON LOGICALLY INCONSISTENT SPECIAL VERDICTS EFFECTIVELY DENIES PETITIONER A FAIR JURY TRIAL IN AN IMPORTANT AND GROWING CLASS OF CHILDHOOD VACCINE INJURY CASES, THREATENS THE VIABILITY OF A HIGHLY EFFECTIVE NATIONAL PUBLIC HEALTH PROGRAM, AND CONFLICTS WITH DECISIONS IN OTHER CIRCUITS

A. Judicial Tolerance of Inconsistent Special Findings In Technically Complex And Emotionally Charged Vaccine Injury Cases Threatens The Viability Of An Effective Public Health Program

The United States is in the midst of an unprecedented explosion of vaccine liability litigation. There are currently hundreds of suits pending—most of which involve the DTP vaccine—with damage claims totaling several billion dollars,[10] or about ten times the annual sales of the entire vaccine industry.[11] In an *amicus* brief to the Court of Appeals for the Fourth Circuit, the United States recently emphasized that the imposition of liability on DTP manufacturers under a design defect theory such as that applied in the lower courts here, notwithstanding federal approval and licensing of the whole-cell vaccine, threatens to undermine essential public health programs fostered and financed by the federal government.[12] Many

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[10] *See Childhood Immunization*, 99th Cong., 2d Sess. (Comm. Print 1986) at 85-86.

[11] *See* Institute of Medicine, *Vaccine Supply and Innovation* (1985).

[12] *See* HHS *Amicus* Brief at 7-9, Appendix E at 88a-90a. The federal government itself purchases and distributes the whole-cell vaccine. In one recent twelve-month period, the federal government purchased nine million doses of the whole-cell vaccine, *see* HHS *Amicus* Brief at 19 n.12, Appendix E at 97a n.12, or about 45% of all the DTP vaccine administered in that period.

manufacturers have stopped researching and producing childhood vaccines,[13] and only four domestic companies currently do so.[14] Only two companies, petitioner Lederle and Connaught Laboratories, Inc. (a subsidiary of a Canadian company), manufacture and market the DTP vaccine in the United States.[15]

This case is typical of much DTP litigation. The development of a tragic illness by an innocent child following a vaccination results in a suit being filed against the vaccine manufacturer alleging that the "whole-cell" pertussis vaccine caused the injury and that the manufacturer could have produced a safer, effective non-whole-cell vaccine but chose not to do so. The plaintiff then presents to the jury a case consisting of complex scientific evidence concerning the relationship between the vaccine and the injury and concerning the feasibility of alternative vaccine designs. The defendant presents complex scientific evidence to disprove any causal relationship between the vaccine and the injury [16] and to show the current unfeasibility of effective alternative designs. Typically, the jury also hears evidence of the government's role in ap-

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[13] *See* HHS *Amicus* Brief at 7-8, Appendix E at 88a-89a; *see also* H.R. Rep. No. 99-908, 99th Cong., 2d Sess. (1986), Part 1, at 4.

[14] *Childhood Immunizations, supra,* at 67.

[15] A third company, Wyeth Laboratories, Inc., until recently manufactured a DTP vaccine. In addition, the state health laboratories in Michigan and Massachusetts produce DTP vaccines for use in their respective states. The DTP vaccines produced by Connaught, Wyeth, Michigan and Massachusetts are all of the "whole-cell" design that the jury below determined to be a negligent design. *See* HHS *Amicus* Brief at 7-8 & nn.5-6, Appendix E at 88a-89a & nn.5-6.

[16] The injuries allegedly caused by the whole-cell pertussis vaccine are common among young children even in the absence of vaccine administration. Since young children receive pertussis vaccine as frequently as five times between the ages of two months and two years, there is frequently an issue of fact as to whether the occurrence of the injury following an inoculation proves that the vaccine caused the injury.

proving and licensing the whole-cell vaccine, and of the extraordinary gains that have been made in combatting and controlling pertussis through the widest feasible administration of the whole-cell vaccine.

In the emotionally charged atmosphere of a trial involving a serious injury to a young child, jurors would be less than human not to feel some desire to compensate the occasional innocent person who suffers injury after being inoculated with a vaccine, even though that vaccine protects those receiving it against life-threatening disease. In these circumstances, strict judicial supervision of juries, through carefully worded instructions and special interrogatories and careful comparison of the verdicts with the evidence, is essential. The temptation to render an inconsistent verdict in order to compensate the innocent injured person is too palpable to ignore.[17]

The jury in this case, for example, while finding that Lederle's whole-cell vaccine was not unreasonably dangerous, also found Lederle negligent for not designing a safer and equally effective vaccine. The jury apparently considered this an acceptable way to compensate the injured child without condemning an essential medical product.[18]

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[17] When the *Toner* verdict was rendered, there was no federal program of no-fault compensation for persons in Toner's position. In 1986, however, Congress passed the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa *et seq.*, authorizing no-fault federal compensation not only to future sufferers of vaccine injury, but also to persons who had lost suits for injuries suffered before the effective date of the act (recently established as October 1, 1988, *see* Vaccine Compensation Amendments of the Omibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 9712). 42 U.S.C. § 300aa-11(4). The Toner child would be eligible to apply for compensation under the act even if respondents are ultimately unsuccessful in this suit.

[18] Respondents' trial exhibits 100-105 demonstrate that the amount awarded by the jury was slightly less than the total sought for medical care and lost earnings. The jury awarded no compensation for alleged "pain and suffering" or any punitive damages.

This Court requires that inconsistent verdicts be reconciled if reconciliation is possible "under a fair reading of them," *Gallick v. Baltimore & Ohio R. Co.*, 372 U.S. 108, 119 (1963).[19] The court below, however, went further than a "fair reading." It applied a standard that seems to call for reconciliation whenever a theoretical framework for reconciliation is "not beyond peradventure." Such a loose standard virtually abdicates judicial supervision of the jury's application of the law to the facts. Inconsistent verdicts, particularly in cases that are threatening the viability of a national health program, should not be reconciled just because a construct for reconciliation is not beyond the realm of possibility.[20] Rather, "there must be a limit where . . . the special verdicts are quite irreconcilable, the plaintiff's case is tenuous, and the suspicion strong that the judgment was predicated upon confusion or sympathy or both." *Bernardini v. Radari A/B Saturnus*, 512 F.2d 660, 664 (2d Cir. 1975).

Under any "fair reading," the jury's verdicts below crossed that limit. The logic of the analysis is simple and inescapable: The court of appeals interpreted the jury instructions as including an implicit instruction "to decide whether Tri-Immunol was an unavoidably unsafe product."[21] 828 F.2d at 512, Appendix A at 5a. It must be presumed that the jury resolved that question one way or the other. If the jury had found that the whole-cell Tri-Immunol was *avoidably* unsafe, and therefore that Lederle was negligent in not designing a safer

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[19] When inconsistent verdicts are rendered by a federal jury, the reconcilability of the verdicts is a question of federal law. *See Toner*, 779 F.2d at 1434, Appendix B at 19a.

[20] The Oxford English Dictionary defines "peradventure" as "1. The possibility of a thing being so or not; uncertainty, doubt; a contingency; a conjecture, chance, hazard."

[21] Indeed, the court expressed concern that absent such an instruction the jury instructions would have been inadequate. *See* 828 F.2d at 512, Appendix A at 4a-5a; 779 F.2d at 1432, Appendix B at 16a.

and equally effective alternative, it could not logically have concluded that Tri-Immunol was not *unreasonably* dangerous. If the jury found, as it did, that Tri-Immunol was not unreasonably dangerous (the inescapable equivalent of "*unavoidably* unsafe") it could not logically have concluded that Lederle was negligent for failing to make a safer and equally effective alternative.[22]

Vaccine liability litigation has reduced the supply and greatly increased the cost of important vaccines. The problem need not be compounded, however, by a judicial reluctance to exercise proper supervision over the jury factfinding process. If the decision of the court below stands, it is likely to become the source of even further confusion and conflict as plaintiffs begin to request jury instructions that inconsistent findings of the *Toner* type are acceptable, and as trial and appellate judges address the issue of reconciling such inconsistent findings. In the meantime, vaccine manufacturers' resources will be pointlessly drained until, ultimately, essential vaccines become unaffordable or altogether unavailable.

Two recent vaccine developments underline the national importance of clarifying federal procedural law about the permissibility of simultaneous jury findings that a beneficial product is not unreasonably dangerous (*i.e.*, unavoidably unsafe) but is nevertheless negligently designed:

> First, plaintiffs in other Tri-Immunol cases have pleaded the *Toner* verdict as a collateral estoppel

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[22] The court of appeals tried to avoid this dilemma by shunning its own holding that the jury was instructed to decide the comment k "unavoidably unsafe" question. In interpreting the jury's strict liability verdict as focusing only on whether "the danger posed by the product itself was not greater than an ordinary consumer would reasonably expect," 828 F.2d at 513, Appendix A at 7a, the court suggested that the jury addressed only the question *whether Tri-Immunol was as safe as an ordinary consumer would expect a whole-cell vaccine to be*, wholly apart from the question of whether a safer vaccine could be made. It is this latter question, however, that is the crux of the comment k issue.

against Lederle on the issue of negligent design.[23] In ruling on those motions, courts must, among other things, interpret the *Toner* verdict, as affirmed by the court of appeals below, and decide whether it is sufficiently clear and consistent on the negligent design issue to justify invoking collateral estoppel and precluding Lederle from trying the comment k negligent design issues before other courts and juries. In deciding the collateral estoppel question, these other courts may themselves read the inconsistent *Toner* special verdicts in conflicting ways and therefore reach conflicting results—a situation which could be avoided by resolving here and now whether the *Toner* verdict is void for inconsistency or not. Moreover, to the extent that they give *Toner* collateral estoppel or precedential effect, they may so increase manufacturers' liability costs as to price essential vaccines beyond the reach of most purchasers, or even drive them off the market.[24]

Second, in Section 2212(b)(1) and (2) of the 1986 Vaccine Injury Compensation Act,[25] Congress has provided a federal defense in state law tort cases for injuries allegedly caused by federally approved vaccines administered after October 1, 1988.[26] That defense is substantially equivalent to the "unavoidably unsafe" rule of ALI Restatement of Torts Section 402A comment k. Unless the inconsistent verdict issue is resolved promptly, it is likely to recur again and again in future vaccine injury cases in

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[23] *See, e.g.*, Plaintiff's Brief on Partial Summary Judgment in *Cunningham v. Lederle Laboratories*, No. 86-144 (D.Mont., filed Nov. 1, 1987).

[24] The most recent jury verdict based on a finding of negligent design of the whole-cell pertussis vaccine was for 15 million dollars in compensatory damages. *See Graham v. Wyeth Laboratories*, No. 85-1481-K (D. Kan. Oct. 15, 1987).

[25] 42 U.S.C. §§ 300aa-22(b)(1), 300aa-22(b)(2).

[26] This effective date was established by the Vaccine Compensation Amendments in the Omnibus Budget Reconciliation Act of 1987. *See supra* note 17.

which this federal law defense is invoked. The longer the delay in authoritatively resolving that issue, the greater will be the likelihood that whole-cell pertussis vaccine will be driven off the market before a safer and equally effective alternative pertussis vaccine can be developed, clinically tested and licensed as safe and effective for use.

B. The Lower Court's Reconciliation Of A Jury Finding Of Negligent Design With Jury Findings Of No Strict Liability And No Breach Of Warranty Conflicts With Other Circuits' Determinations That Such Verdicts Cannot Be Reconciled

The decision below conflicts with the reasoning and conclusions of both the Eleventh Circuit, in *Witt v. Norfe, Inc.*, 725 F.2d 1277 (11th Cir. 1984), and the Eighth Circuit, in *McIntyre v. Everest & Jennings, Inc.*, 575 F.2d 155 (8th Cir.), *cert. denied*, 439 U.S. 864 (1978). All three decisions involve the application of identical federal procedural principles in diversity cases in which the substantive rules of decision are derived from different bodies of state law. *See Gallick v. Baltimore & Ohio R. Co.*, 372 U.S. 108 (1963).

In *Witt*, the plaintiff received injuries when a shower door shattered. Plaintiff sued the manufacturer on theories of negligence, strict liability, and breach of warranty of merchantability. The jury returned special verdicts finding that the door was not unreasonably dangerous and that it was fit for its intended use, thus exonerating defendant on the strict liability and breach of warranty claims. The jury did, however, find defendant negligent in designing the door, and the trial court entered judgment for plaintiff. *See* 725 F.2d at 1278.

The Court of Appeals for the Eleventh Circuit reversed and remanded the case for a new trial on the ground that the verdicts were irreconcilable and that the court "could not speculate which inconsistent finding the jury intended to be controlling." The court reviewed the applicable state law—indistinguishable from the appli-

cable law of Idaho in the instant case[27]—and considered whether the manufacturer could have been negligent in designing the door without the resulting design defect rising to the level of making the door unreasonably dangerous. The court explicitly rejected that reconciliation, however, and concluded that "it must be deemed inconsistent for a jury to find that a product was not defective for purposes of strict liability, and yet that the product was negligently designed . . . ." 725 F.2d at 1279.

The *Witt* court went on to hold that even if the negligence and strict liability findings were to be reconciled by positing that the jury had mistakenly believed "that a design defect sufficient to satisfy a negligence claim would not necessarily be dangerous enough to meet strict liability standards," the jury's finding on the *warranty* claim would still present an inconsistency. In the court's view, the findings on strict liability and breach of warranty indicated that the jury believed that "the shower door was neither dangerously defective nor unfit for its intended use or any reasonably foreseeable use . . . ." 725 F.2d at 1280. The court concluded that these findings were "irreconcilably" in conflict with the jury's finding of negligence. *Id.*

The instant case cannot be distinguished from *Witt*. Given virtually the same state substantive law and the same inconsistent special verdicts, the court below reached a conclusion precisely opposite the *Witt* court.

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[27] Both Florida law, at issue in *Witt*, and Idaho law, incorporate Restatement of Torts (2d) § 402A and comment k on strict liability. *See Witt*, 725 F.2d at 1278-79; *Toner*, 732 P.2d at 304, 308, Appendix C at 34a, 39a-40a. The two states also have indistinguishable formulations for negligence. In Florida, "a manufacturer is held to a standard of reasonable care in the design of its products, so that they will be reasonably safe for use in a foreseeable manner." *Witt*, 725 F.2d at 1278. In Idaho, a manufacturer must "exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products." *Toner*, 732 P.2d at 312, Appendix C at 47a.

Indeed, the court below adopted the very reconciliation that the *Witt* court expressly rejected. *Compare* 828 F.2d at 513, Appendix A at 7a (reasoning that jury may have thought defendant's failure to design vaccine differently was unreasonable, and therefore negligent, while at the same time thinking that the product itself was not unreasonably dangerous) *with* 725 at 1279 (rejecting reasoning that jury might have thought defendant's failure to design door differently was unreasonable and at the same time thought that the product itself was not unreasonably dangerous).[28]

Indeed, the court below seemed to recognize that its decision conflicted with *Witt*, and attempted to distinguish that case. What the court called a distinction, however, appears to be based on a misreading of *Witt*:

> [In *Witt*] the manufacturer of a glass shower door could not have been negligent in its *production* if the product were fit for its intended purpose as found by the jury. In the case before us, the jury could have believed that the vaccine was not per se unfit for its intended use but that Lederle was negligent in failing to develop the alternative.

828 F.2d at 514, Appendix A at 8a (emphasis added). In fact, however, the *Witt* court was speaking of the shower door's negligent *design*, not its negligent production. If the word "design" is substituted for "production" in the first sentence of the above quotation, the quotation is a *non-sequitur*.

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[28] Similarly, the reconciliation of the negligence finding and the warranty finding by the court below directly conflicts with the corresponding determination by the *Witt* court. *Compare* 828 F.2d at 514, Appendix A at 8a (reasoning that jury may have thought that vaccine was "fit for the purposes for which it was to be used," and at the same time thought that defendant was negligent in not designing it differently) *with* 725 F.2d at 1279-80 (reasoning that finding product "reasonably fit for the intended use" was inconsistent with finding of negligent design).

The Eighth Circuit, in *McIntyre v. Everest & Jennings, Inc.*, 575 F.2d 155 (8th Cir.), *cert. denied*, 439 U.S. 864 (1978), reached the same conclusion as the *Witt* court. In *McIntyre*, the jury found that the defendant was negligent in connection with a commode it manufactured, but found for the defendant on the question of strict liability. Because the negligence claims in *McIntyre* included a claim of failure to warn, the court of appeals did not find those verdicts necessarily inconsistent.[29] The court did, however, hold [30] that

> The jury's finding in favor of the defendant on the issue of strict liability precludes a finding of negligent design of an unstable commode or a negligent failure to perform tests of the commode's stability characteristics in this particular case. The only basis on which the jury's verdict could lie is either in a failure to warn or instruct on the commode's propensity to tip when the user leaned forward.

575 F.2d at 159.

Certiorari should be granted to resolve these conflicts.

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[29] As the *McIntyre* court noted, and as petitioner has conceded throughout, under comment k principles a finding of negligent failure to warn, as distinguished from a finding of negligent design, is not inconsistent with a finding that a product is not unreasonably dangerous. *See* 575 F.2d at 159 & n.1.

[30] Because the court went on to reverse the judgment on the ground that there was insufficient evidence on the failure to warn claim, the quoted passage must be considered as a holding rather than as dicta.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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January 11, 1988

APPENDICES

APPENDIX A

UNITED STATES COURT OF APPEALS
NINTH CIRCUIT

No. 84-3906

DAVID TONER, Guardian ad litem for KEVIN TONER, an infant child, and David Toner and Susan Toner, husband and wife, individually,

Plaintiffs-Appellees,

v.

LEDERLE LABORATORIES, A DIVISION OF AMERICAN CYANAMID CO., a corporation,

Defendant-Appellant.

Argued and Submitted April 4, 1985
Decided Sept. 16, 1987

Appeal from the United States District Court for the District of Idaho.

Elam, Burke, Evans, Boyd & Koontz, Robert J. Koontz, Boise, Idaho, for defendant-appellant.

Webb, Burton, Carlson, Pedersen & Webb, Kenneth L. Pedersen, Curtis R. Webb, Twin Falls, Idaho, Richard D. Polling, Charlotte, N.Car., for plaintiffs-appellees.

Before WRIGHT, KENNEDY and ANDERSON, Circuit Judges.

KENNEDY, Circuit Judge:

This products liability case presented questions of state law which we certified to the Idaho Supreme Court. *Toner v. Lederle Laboratories*, 779 F.2d 1429 (9th Cir. 1986). That court having issued a full opinion in response to the certification, *Toner v. Lederle Laboratories*, 112 Idaho 328, 732 P.2d 297 (1987), we now complete our disposition of the appeal, and we affirm the judgment for the plaintiff based on the jury's finding of negligence.

The facts are set forth in detail in our previous opinion. 779 F.2d at 1430-31. Kevin Toner, the plaintiff in the trial court, was paralyzed after vaccination with Tri-Immunol, a vaccine manufactured by the defendant, Lederle Laboratories. A state court action commenced by the plaintiff's parents was removed to federal court based on diversity of citizenship. 28 U.S.C. § 1441 (1982). The plaintiff's principal contention was that Lederle had failed to develop and market Tri-Solgen, an alternative vaccine that would have been safer than the one given to him. In a special verdict, the jury found that Lederle was negligent in connection with the product, and that the negligence was the proximate cause of the plaintiff's injuries. In further special verdicts, the jury rejected the plaintiff's alternative theories of strict liability and breach of warranty. The jury awarded $1,131,200 in damages on the negligence claim. *See* 779 F.2d at 1433.

On appeal Lederle argues that the jury instructions on negligence were inadequate for failure to state that certain drugs are unavoidably unsafe and that it is permissible to market such products despite risks inherent in their use. *See Restatement (Second) of Torts* § 402A comment k (1965). Lederle also contends that the jury's rejection of Toner's strict liability claim necessarily is a conclusion that any defect in the product was unavoidable, which, at least on the facts of this case, is fatally inconsistent with a finding that Lederle was negligent in its manufacture or distribution. We examine these argu-

ments in light of Idaho's response to our certified questions.

The Idaho Supreme Court reformulated our certified questions as follows:

> (1) Under Idaho law, do the principles set forth in Restatement (Second) of Torts § 402A comment k (1965) apply to strict liability claims, and in particular to the claim in this suit?
>
> (2) (a) Under Idaho law, do the principles set forth in Restatement (Second) of Torts § 402A comment k apply to negligence claims, and in particular to the claim in this suit?
>
> (b) If the above question no. (2) (a) is answered affirmatively, did the trial court's instructions on negligence sufficiently incorporate those principles?

732 P.2d at 303. The answers to these questions suffice to dispose of the first issue raised by Lederle, the sufficiency of the negligence instructions; and guide us further in the determination whether the jury verdicts are inconsistent. We conclude the jury instructions on negligence were sufficient under Idaho law and that the jury's special verdicts were not inconsistent.

The opinion of the Idaho Supreme Court discloses that Idaho adheres to the "unavoidably unsafe product" defense, as set forth in comment k, in strict liability cases based on defective design. 732 P.2d at 308. The doctrine recognizes that some products pose inherent risks, but that the benefits outweigh the risks inherent in their intended use, so that strict liability will not be imposed. Under Idaho law, as in most states, however, the plaintiff may proceed under a negligence cause of action even if comment k provides a defense to strict liability. *Id.* at 303 n. 5, 309-10. Quoting a decision of the Washington Supreme Court, the Idaho court in the case before us states that "[n]egligence and strict liability are not mutually exclusive because they differ in focus: negli-

gence focuses upon the conduct of the manufacturer while strict liability focuses upon the product and the consumer's expectation." *Id.* at 303 n. 5 (quoting *David v. Globe Mach. Mfg. Co.*, 102 Wash.2d 68, 684 P.2d 692, 696 (1984)).

The court also tells us that analysis under comment k is similar to negligence analysis in a general sense:

> under negligence analysis, the utility of the act depends upon the value of the interest advanced, the extent to which it is advanced, and the opportunity for a less dangerous course of conduct. Restatement (Second) of Torts § 292 (1965), just as comment k's application depends on the value of the product's benefit, the extent to which the benefit accrues, and the availability of a feasible alternative design. The risks too are similarly considered by comment k and negligence law. *See* Restatement (Second) of Torts § 293 (1965). Such a weighing is implicit in the duty to use due care to avoid injuries while rendering services. *Stephens v. Stearns*, 106 Idaho 249, 257, 678 P.2d 41, 49 (1984). In sum, the determination under comment k that the design of a product is unavoidably unsafe and yet affords benefits outweighing its risks varies little from the determination under negligence law that the designing and marketing of the product was reasonably done.

732 P.2d at 310-11. The opinion states in summary that the jury instructions on negligence adequately enabled the jury to consider all the relevant factors. *Id.* at 311-12.

The decision of the Idaho Supreme Court allows us to hold with confidence that the jury's determination of negligence was reached in accordance with Idaho law and that Lederle is not entitled to judgment on the negligence issue. The instruction on negligence permitted the jury to assess the reasonableness of Lederle's conduct

"in light of all the attendant circumstances," *id.* at 312, among which were the state of scientific knowledge and the utility of the Tri-Immunol vaccine in light of alternatives known by Lederle to be available. The concern we expressed in our prior opinion, that "the trial court may have omitted a material element of negligence in failing to instruct the jury to decide whether Tri-Immunol was an unavoidably unsafe product," 779 F.2d at 1432, has been allayed.

We turn to the issue of whether the jury's special verdicts are fatally inconsistent. We are bound to find the special verdicts consistent if we can do so under a fair reading of them. *Gallick v. Baltimore & Ohio R. Co.*, 372 U.S. 108, 119, 83 S.Ct. 659, 666, 9 L.Ed.2d 618 (1963); *Atlantic & Gulf Stevedores, Inc. v. Ellerman Lines, Ltd.*, 369 U.S. 355, 364, 82 S.Ct. 780, 786, 7 L.Ed. 2d 798 (1962); *Blanton v. Mobil Oil Corp.*, 721 F.2d 1207, 1213 (9th Cir.1983), *cert. denied*, 471 U.S. 1007, 105 S.Ct. 1874, 85 L.Ed.2d 166 (1985). When faced with a claim that verdicts are inconsistent, the court must search for a reasonable way to read the verdicts as expressing a coherent view of the case, and must exhaust this effort before it is free to disregard the jury's verdict and remand the case for a new trial. *Gallick*, 372 U.S. at 119, 83 S.Ct. at 666. The consistency of the jury verdicts must be considered in light of the judge's instructions to the jury. *Id.* at 120-21, 83 S.Ct. at 666-67; *Bates v. Jean*, 745 F.2d 1146, 1151 (7th Cir.1984).

The crux of the inconsistency issue is whether the jury could have found that Lederle was not strictly liable on the ground that Tri-Immunol was an unavoidably unsafe product, but also found that Lederle was negligent in failing to develop the Tri-Solgen vaccine. A similar inconsistency is alleged to exist between the negligence verdict and the finding that Lederle did not breach the implied warranty of merchantability. Lederle contends that under Idaho law, the jury's findings on the strict liability and breach of warranty issues necessarily con-

stitute a finding that the Tri-Immunol vaccine was not defective. Lederle then asks how the jury could possibly have found Lederle negligent in marketing a nondefective product, especially when the balancing of risk versus utility that makes the product nondefective is similar to the analysis used to determine the reasonableness of the manufacturer's conduct. *See Toner*, 732 P.2d at 310-11.

Although we recognize the abstract symmetry of Lederle's argument, we must adhere to our duty to reconcile the jury verdicts if there is a reasonable way to do so. In light of the Idaho Supreme Court's opinion and the instructions actually given to the jury, we think Lederle's paradox can be resolved and the jury's verdicts reconciled. As the Idaho Supreme Court points out, the focus in negligence is on the manufacturer's conduct, while in strict liability it is on the product and the user's expectations. *Id.* at 303 n. 5; *Rojas v. Lindsay Mfg. Co.*, 108 Idaho 590, 592, 701 P.2d 210, 212 (1985). Comment k functions in the strict liability context to encourage production and marketing of useful products, but it does not remove the incentive for safe design by the manufacturer that is supplied by the threat of negligence liability. 732 P.2d at 310. The instruction given to the jury on the meaning of the strict liability term "defective condition, unreasonably dangerous" reflects this focus:

> "Instruction No. 21: A product is in a defective condition, unreasonably dangerous to persons if it is more dangerous than would be expected by an ordinary person who may reasonably be expected to use it. The law does not say what would be expected by an ordinary person or who may reasonably be expected to use the product. Both of these are for you to decide."

This focus is different from the emphasis in the instruction on negligence, which is phrased in terms of the manufacturer's duty to "exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm."

It is not enough for Lederle to argue that the jury's finding of negligence concludes that Tri-Immunol was defective, while its finding on strict liability states a contrary view. The law and the instructions required the jury to examine the case from two different points of view. It is reasonable to read the special verdicts as saying that Lederle's failure to develop the Tri-Solgen vaccine was unreasonable conduct, although the danger posed by the product itself was not greater than an ordinary consumer would reasonably expect.

Lederle contends that even accepting the differing focus of the jury instructions, Toner's failure to pursue his strict liability claim of inadequate warning means that the ordinary user of the product must be assumed to have all the information available to Lederle. This being so, Lederle claims, the reasonableness determination in strict liability mirrors the reasonableness determination in negligence, and the verdicts are inconsistent. We disagree.

As an initial matter, we doubt that Lederle is entitled to treat the case as if the jury found adequate warning; the issue was not before it. We decline to treat Toner's litigation decision not to pursue the warning theory as if it were a stipulation that Toner had adequate warning. Even if the jury had reached such a verdict, the vantage point of the ordinary consumer in the strict liability instruction would not be identical to the vantage point of the manufacturer itself. Such a rule would do away with the distinction between strict liability and negligence set forth by the Idaho Supreme Court, does not comport with the strict liability instruction that was given to the jury, which specifically stated that "the law does not say what would be expected by an ordinary person."

Similarly, we do not think the jury's verdict on the negligence issue is necessarily inconsistent with its finding that Lederle did not breach the implied warranty of merchantability. On that issue, the jury was instructed

that "a breach of this warranty occurs when the product is not fit for the ordinary purposes for which the product is to be used." It is not beyond peradventure that the jury thought that Tri-Immunol was fit for the purposes for which it was to be used, but that Lederle was negligent in failing to replace it with a better product. This case is distinguishable from *Witt v. Norfe*, 725 F.2d 1277, 1279-80 (11th Cir.1984), in which the manufacturer of a glass shower door could not have been negligent in its production if the product were fit for its intended purpose as found by the jury. In the case before us, the jury could have believed that the vaccine was not per se unfit for its intended use but that Lederle was negligent in failing to develop the alternative. The jury's verdicts rendered pursuant to the instructions as given are amenable to an interpretation that makes them consistent.

Finally, we reject Lederle's claim that the plaintiffs failed to show that Lederle's negligence was an actual or proximate cause of the plaintiff's injury. Much of the testimony at trial centered on whether the injury would have occurred but for Lederle's failure to utilize the Tri-Solgen vaccine. There was expert testimony that it would not have. We reject Lederle's argument that the plaintiff failed to prove causation because he failed to show that Tri-Solgen would have been approved by the FDA. The Third Circuit has determined that this issue is for the jury, keeping in mind the FDA's statutory duty to monitor drugs for safety and effectiveness. *Stanton v. Astra Pharmaceutical Prods.*, 718 F.2d 553, 569 (3rd Cir.1983). We agree. The testimony by witnesses for both sides regarding the length of time that the Tri-Solgen vaccine was available and the absence of evidence that the FDA would not have approved it had Lederle submitted the product was sufficient to permit the jury to infer that Toner's injury could in fact have been avoided by the Tri-Solgen vaccine.

Were we charged with deciding whether jury verdicts are the most sensible way of allocating risks and costs regarding vaccines that have been proved beneficial, we might well design a different method. The question, however, is one of Idaho law. The Idaho Supreme Court enforces the traditional tort system, leaving for its legislature any comprehensive reform. We must defer to this state law determination.

AFFIRMED.

APPENDIX B

UNITED STATES COURT OF APPEALS
NINTH CIRCUIT

No. 84-3906

DAVID TONER, Guardian ad litem for KEVIN TONER, an infant child, and DAVID TONER and SUSAN TONER, husband and wife, individually,
Plaintiffs-Appellees,

v.

LEDERLE LABORATORIES, A DIVISION OF AMERICAN CYANAMID CO., a corporation,
Defendant-Appellant.

Argued and Submitted April 4, 1985
Decided Jan. 7, 1986

Appeal from the United States District Court
for the District of Idaho

Kenneth L. Pederson, Twin Falls, Idaho, for plaintiffs-appellees.

Robert J. Koontz, Elam, Burke, Evans, Boyd, & Koontz, Boise, Idaho, for defendant-appellant.

Before WRIGHT, KENNEDY, and ANDERSON, Circuit Judges.

KENNEDY, Circuit Judge:

This products liability action involves Tri-Immunol, appellant Lederle Laboratories' triple antigen vaccine used to immunize children against diphtheria, pertussis, and tetanus (DPT). Lederle, the only American distributor of the vaccine, contends that the evidence presented to the jury was insufficient to support a finding that it was negligent in the design, manufacture, and distribution of the vaccine. Resolution of this appeal requires us to address unsettled questions of Idaho law, and we deem it appropriate to permit the judicial system of that state to address those matters. We therefore defer decision of this case and certify four questions raising state law issues to the Idaho Supreme Court. *See* Idaho App. R. 12.1 (Supp.1985).

In 1979, Kevin Toner, then a three-month-old infant, was vaccinated with Tri-Immunol and suffered a rare condition of the spine known as transverse myelitis, the cause of which is unknown. As a result of the affliction, Kevin is permanently paralyzed from the waist down. His parents commenced litigation in Idaho state court, and appellant removed the case to federal court on the basis of diversity of citizenship. 28 U.S.C. § 1441 (1982). The suit was tried to the jury on theories of strict liability, negligence, breach of warranty of merchantability, and failure to warn. Appellees withdrew the failure to warn claim before the case was submitted to the jury. The jury found that the pertussis component of the vaccine had caused Kevin's paralysis; although in a special verdict the jury rejected the strict liability and breach of warranty claims, it found appellant negligent and assessed damages of $1,131,200.

In the early years of this century, pertussis was one of the leading causes of death in children. In recent years, however, the widespread availability of vaccines such as that marketed by defendant has virtually eradicated the disease. An instructive, brief description of

common vaccines is found in an opinion by the Second Circuit, *Ezagui v. Dow Chemical Corp.*, 598 F.2d 727, 731 (2d Cir.1979), and we rely upon that description for the following background explanation.

By introducing an antigenic factor into the body, vaccines stimulate the production of antibodies that protect against disease. Some infectious organisms, such as those causing diphtheria and tetanus, excrete soluble toxins insolable by medical research. The toxin is inactivated with formaldehyde and transformed into a toxoid. The toxoid is then used in a vaccine, as it can immunize against disease by stimulating the production of antibodies in the recipient, even though it has lost its own poisonous qualities.

This is not the case, however, with vaccines such as Tri-Immunol. Tri-Immunol is a so-called whole cell vaccine because it contains whole killed pertussis organisms. The whole organism is used because the pertussis organism contains fifteen or sixteen different antigens, and medical science has yet to isolate the one that stimulates protection against the disease. *See Tinnerholm v. Parke Davis & Co.*, 411 F.2d 48, 50 (2d Cir.1969). Courts that have addressed the issue of liability for adverse reactions to the DPT vaccine have commented that "the bacterial organism which causes pertussis is so complex as to make impossible the isolation and deactivation of the toxin or poison." *Ezagui*, 598 F.2d at 731; *accord Tinnerholm*, 411 F.2d at 50. Because of this difficulty, at the time of Kevin Toner's vaccination, the whole cell pertussis vaccine was the only pertussis vaccine licensed by the Food and Drug Administration (FDA) for use in the United States. It remains the only licensed vaccine today.

The whole cell pertussis vaccine is neurotoxic and can cause adverse reactions. These reactions are of two types: local and severe. Local reactions include swelling, fever, irritability, and crying spells. Severe reactions

include encephalopathy, paralysis, and even death. The expected rate of severe reactions ranges between one in 100,000 and one in 310,000 doses. Prior to this incident, there had been only one case of transverse myelitis reported in connection with a DPT vaccine.

During the 1950's, the Eli Lilly Company developed a fractionated cell pertussis vaccine called Tri-Solgen that was prepared by treating whole killed pertussis cells with salt. Early studies indicated that this method of preparation resulted in a less toxic vaccine, and following its approval by the FDA in 1967, Tri-Solgen occupied a substantial share of the market. Lilly withdrew from the vaccine business in 1975 and stopped producing Tri-Solgen. Lilly sold the right to produce Tri-Solgen to Wyeth Laboratories; however, the FDA has refused to relicense the vaccine.

Lederle was aware of the neurotoxicity of Tri-Immunol as early as the 1950's and since that time has received occasional reports of severe adverse reactions to the vaccine. Following FDA approval of Tri-Solgen, Lederle conducted an internal study comparing Tri-Immunol with Tri-Solgen in an effort to determine whether to develop its own fractionated cell product. The study found fewer local reactions associated with Tri-Solgen, but it noted no severe reactions in either cohort due to the restricted number of subjects studied. At trial, Dr. Frank Cano, the Manager of Biologics at Lederle, testified that the differences observed in the study lacked statistical significance. Lederle only experimented with the production of a fracionated cell product until 1975. Since then, Japan has developed a pertussis toxoid vaccine, and Lederle's research efforts to achieve that objective may reach fruition within the next few years.

The principal thrust of appellees' negligence argument at trial concerned Lederle's failure to develop a fractionated cell product. In support of this theory appellees contend that Tri-Solgen was shown to be a safer yet equally efficacious pertussis vaccine. Appellees' experts

testified that the whole cell vaccine was five times more reactive than the fractionated cell product, and that early studies indicated that Tri-Solgen caused fewer local reactions than the whole cell vaccine. The studies did not establish, however, that Tri-Solgen caused fewer severe reactions than the whole cell vaccine. With regard to efficacy, appellees produced four studies that found that fractionated cell products produced an immune response to pertussis. However, in 1972, a review panel within the Bureau of Biologics of the FDA refused to certify Tri-Solgen as "safe and effective" although it did so certify the whole cell vaccines. Because the FDA has refused to relicense Tri-Solgen or any other fractionated cell product, the manufacture and sale of such a vaccine by Lederle, or any other pharmaceutical company, would constitute a criminal offense under the Food, Drug and Cosmetic Act. *See* 21 U.S.C. §§ 331(d), 333(a), 355(a) (1982).

Appellant contends that a basis for negligence was not established in this case. Although the question of the sufficiency of the evidence is a procedural matter governed by federal law, *Glovatorium, Inc. v. NCR Corp.*, 684 F.2d 658, 660 (9th Cir. 1982), we must look to the substantive law of the State of Idaho to determine the elements of plaintiffs' cause of action. *Neely v. St. Paul Fire & Marine Insurance Co.*, 584 F.2d 341, 345 (9th Cir.1978).

> The trial judge instructed the jury that: A manufacturer of vaccines has the duty to exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products. The failure to meet this standard of due care in light of all the attendant circumstances will constitute negligence and subject the manufacturer to liability for the resulting consequences. The fact that the consumer's injuries were proximately caused by the manufacturer's product does not in and of itself constitute a sufficient basis upon which to predicate the manufacturer's liability.

> When the cause of action sounds in negligence, a manufacturer's duty to additionally test and investigate the propensities of its product is dependent upon the foreseeable risk of harm to potential users in light of then current scientific or medical knowledge and discoveries.

Appellant argues that the instruction is insufficient because it does not recognize that certain drugs have unavoidable risks but must, nevertheless, be used to protect the public health. To support its argument, appellant cites *Restatement (Second) of Torts* § 402A comment k (1965),[1] which recognizes that the marketing of

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[1] Comment k states:

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A comment k (1965).

some drugs is fully justified to prevent disease despite risks inherent in their use. As appellant recognizes, the *Restatement* section and its comment pertain to strict liability; but, appellant argues, the controlling principles are also applicable to the question of liability for negligence.

Though appellees contend that the issue in this case is not the applicability of comment k but, rather, the appellant's alleged negligence in failing to develop a fractionated cell vaccine, we see the questions as related. The concept of an unavoidably unsafe product seems necessarily to depend on whether research was properly pursued. If this is true, the trial court may have omitted a material element of negligence in failing to instruct the jury to decide whether Tri-Immunol was an unavoidably unsafe product.

Various reported decisions of the Idaho Supreme Court succinctly set forth the elements of negligence, *see, e.g., Algeria v. Payonk*, 101 Idaho 617, 619 P.2d 135, 137 (1980); *Brizendine v. Nampa Meridian Irrigation District*, 97 Idaho 580, 548 P.2d 80, 83 (1976), but our research does not disclose an Idaho case that provides definitive guidance on the question of the duty, or standard of care, applicable to the manufacturer of drugs that are unsafe in some respects but that are necessary for the control of disease. The Idaho courts have not yet had the opportunity to address *Restatement (Second) of Torts* § 402A comment k, either in the strict liability or the negligence context. Other relevant Idaho precedents do not indicate whether Lederle's conduct in designing and distributing a vaccine for which there is no legally available substitute and which possesses a degree of social utility may be characterized as negligent.

We use our discretion to certify four questions to the Idaho Supreme Court. *Lehman Brothers v. Schein*, 416 U.S. 386, 391, 94 S.Ct. 1741, 1744, 40 L.Ed.2d 215 (1974). Certification provides a means to obtain au-

thoritative answers to unclear questions of state law. 17 C. Wright, A. Miller & E. Cooper, *Federal Practice and Procedure*, § 4248, at 520 (1978). It "save[s] time, energy, and resources and helps build a cooperative judicial federalism." *Lehman Brothers*, 416 U.S. at 391, 94 S.Ct. at 1744 (footnote omitted); *see also Bellotti v. Baird*, 428 U.S. 132, 150-51, 96 S.Ct. 2857, 2867-68, 49 L.Ed.2d 844 (1976) (quoting *Lehman Brothers*); *Clay v. Sun Insurance Office, Ltd.*, 363 U.S. 207, 212, 80 S.Ct. 1222, 1225, 4 L.Ed.2d 1170 (1960) (certification available to permit resolution of unresolved questions of state law). We have certified questions to the Idaho Supreme Court before. *See, e.g., Waters v. Armstrong World Industries*, 773 F.2d 248, 250-51 (9th Cir.1985); *In re New Concept Realty & Development, Inc.*, 753 F.2d 804, 806 (9th Cir.1985) (per curiam); *Meckert v. Transamerica Insurance Co.*, 742 F.2d 505, 506-07 (9th Cir. 1984). Pursuant to Idaho procedure, we find that the following questions constitute "controlling question[s] of law . . . as to which there is no controlling precedent in the decisions of the Idaho Supreme Court" and that "[a]n immediate determination of the Idaho law with regard to [these questions] would materially advance the orderly resolution of the litigation." Idaho App.R. 12.1(a)(1), (2) (Supp.1985).

(1) Under Idaho law, do the principles set forth in *Restatement (Second) of Torts* § 402A comment k apply to strict liability and negligence claims, and in particular to the claims in this suit?

(2) If yes, is there evidence from which a jury could find Tri-Immunol avoidably unsafe?

(3) Under Idaho law, could the jury, on this record, find the defendant negligent for failure to develop a fractionated cell vaccine, or for any other reason?

(4) Were the jury instructions on the issue of negligence in full accordance with Idaho law, given the contentions of the parties in this case?

We respectfully request the Idaho Supreme Court to exercise its discretionary authority under Idaho Appellate Rule 12.1(c) to accept and decide these questions. Our phrasing of the questions should not restrict the court's consideration of the problems and issues involved. The court may reformulate the relevant state law questions as it perceives them to be, in light of the contentions of the parties. *Meckert*, 742 F.2d at 507. To the extent the court finds it necessary in resolving the issue of negligence to address liability under theories of strict liability or implied warranty of merchantability, it may do so as well. If the Idaho Supreme Court deems the issues presented by this case to be inappropriate for certification, or if it chooses to decline the certification for any other reason, it should so state, and we will resolve the issues according to our perceptions of Idaho law.

Appellant also argues for reversal on the ground that the jury's finding of negligence was inconsistent with its rejection of appellees' allegations of strict liability and breach of implied warranty of merchantability. The jury returned the following five verdicts, each by unanimous vote:

> *QUESTION NO. 1:* Have the plaintiffs proved by a preponderance of the evidence, that Kevin Toner's paralysis was proximately caused by the DPT vaccine manufactured and sold by the defendant Lederle Laboratories? Yes.
>
> *QUESTION NO. 2:* Was defendant Lederle Laboratories negligent in connection with the product Tri-Immunol which was the proximate cause of the plaintiff's injuries? Yes.
>
> *QUESTION NO. 3:* Was the product Tri-Immunol manufactured by the defendant Lederle Laboratories in a defective condition unreasonably dangerous to persons which was the proximate cause of the plaintiff's injuries? No.

QUESTION NO. 4: Did defendant Lederle Laboratories breach an implied warranty of merchantability in connection with the product Tri-Immunol which was the proximate cause of the plaintiff's injury? No.

QUESTION NO. 5: What is the total amount of damages sustained by the plaintiffs as a result of the injuries to Kevin Toner? $1,131,200.

Although the inconsistency claim is ultimately a matter of federal law for this court to decide, we should not decide its merits in advance of the state court's decision on the question of negligence. The jury's responses to the interrogatories are the result of its interpretation of the district court's instructions to it on the elements of negligence, strict liability, and warranty of merchantability. The question whether the trial court instructed the jury in accordance with Idaho law necessarily precedes resolution of the inconsistency claim. If, after the Idaho Supreme Court declares the substantive principles of law that govern the case, it is determined that the district court instructed the jury incorrectly, it may be unnecessary for us to reach the inconsistent verdict claim.

The Clerk will file a certified copy of our Opinion and Order with the Idaho Supreme Court under Idaho Appellate Rule 12.1(b). This panel retains jurisdiction over further proceedings in this court. The parties will notify the Clerk within one week after the Idaho Supreme Court accepts or rejects certification, and again within one week after that court renders its opinion.

So ordered.

APPENDIX C

SUPREME COURT OF IDAHO

No. 16453

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112 Idaho 328

DAVID TONER, guardian ad litem for Kevin Toner, an infant child, and David Toner and Susan Toner, husband and wife, individually,

Plaintiffs-Appellants,

v.

LEDERLE LABORATORIES, A DIVISION OF AMERICAN CYANAMID CO.,

Defendant-Respondent.

[Feb. 4, 1987]

Kenneth L. Pedersen (argued) and Curtis Webb, Twin Falls, for plaintiffs-appellants.

Robert J. Koontz (argued), William J. Batt, and Catherine A. King, Boise, for Lederle Laboratories.

Phillip M. Barber, Boise and Malcolm E. Wheeler (argued), Los Angeles, CA, for amicus curiae, Pharmaceutical Manufacturers Association.

BISTLINE, Justice.

In 1979, plaintiff child Kevin Toner, then three months old, received a vaccination of Tri-Immunol, a drug manufactured by defendant Lederle Laboratories and designed

to immunize children against diptheria, pertussis, and tetanus. Thereafter, Kevin suffered a rare condition of the spine known as transverse myelitis. The affliction permanently paralyzed Kevin from the waist down. Plaintiffs brought suit against Lederle in Idaho state court, but the suit was removed to federal district court on the basis of diversity jurisdiction. At trial, the jury found that Lederle's vaccine has caused Kevin's paralysis and found Lederle negligent, although it rejected plaintiffs' strict liability and breach of warranty claims. Lederle appealed the judgment to the United States Court of Appeals for the Ninth Circuit. Rather than render a decision, pursuant to I.A.R. 12.1 (Supp.1986) the Court of Appeals certified and this Court accepted two controlling questions of Idaho law. These questions center on the role in Idaho strict liability and negligence law of the so-called "unavoidably unsafe" product doctrine, as described in comment k of Restatement (Second) of Torts § 402A (1965) (quoted *infra*, p. 12).

I. BACKGROUND

Toner found much with which to disagree in the Court of Appeals' summary of the facts. Two of the points of contention Toner raised we will set out in footnotes to our quotation of the Court of Appeals' opinion. As we do not have the trial record before us, we must use the Court of Appeals' summary as background to our decision. However, as we will explain below, the posture of the case, which includes a standing jury verdict that Lederle was negligent but that the vaccine was not in a "defective condition unreasonably dangerous to persons," requires certain factual presumptions regardless of the Court of Appeals' recitation.

The Court of Appeals states the facts as follows:

In 1979, Kevin Toner, then a three-month-old infant, was vaccinated with Tri-Immunol and suffered a rare condition of the spine known as transverse myelitis, the

cause of which is unknown. As a result of the affliction, Kevin is permanently paralyzed from the waist down. His parents commenced litigation in Idaho state court, and appellant removed the case to federal court on the basis of diversity of citizenship. 28 U.S.C. § 1441 (1982). The suit was tried to the jury on theories of strict liability, negligence, breach of warranty of merchantability, and failure to warn. Appellees withdrew the failure to warn claim before the case was submitted to the jury. The jury found that the pertussis component of the vaccine had caused Kevin's paralysis; although in a special verdict the jury rejected the strict liability and breach of warranty claims, it found appellant negligent and assessed damages of $1,131,200.

In the early years of this century, pertussis was one of the leading causes of death in children. In recent years, however, the widespread availability of vaccines such as that marketed by defendant has virtually eradicated the disease. An instructive, brief description of common vaccines is found in an opinion by the Second Circuit, *Ezagūi v. Dow Chemical Corp.*, 598 F.2d 727, 731 (2d Cir.1979), and we rely upon that description for the following background explanation.

By introducing an antigenic factor into the body, vaccines stimulate the production of antibodies that protect against disease. Some infectious organisms, such as those causing diptheria and tetanus, excrete soluble toxins insoluble by medical research. The toxin is inactivated with formaldehyde and transformed into a toxoid. The toxoid is then used in a vaccine, as it can immunize against disease by stimulating the production of antibodies in the recipient, even though it has lost its own poisonous qualities.

This is not the case, however, with vaccines such as Tri-Immunol. Tri-Immunol is a so-called whole cell vaccine because it contains whole killed pertussis organisms. The whole organism is used because the pertussis orga-

nism contains fifteen or sixteen different antigens, and medical science has yet to isolate the one that stimulates protection against the disease. *See Tinnerholm v. Parke, Davis & Co.*, 411 F.2d 48, 50 (2d Cir.1969). Courts that have addressed the issue of liability for adverse reactions to the DPT vaccine have commented that "the bacterial organism which causes pertussis is so complex as to make impossible the isolation and deactivation of the toxin or poison." *Ezagui*, 598 F.2d at 731; *accord Tinnerholm*, 411 F.2d at 50. Because of this difficulty, at the time of Kevin Toner's vaccination, the whole cell pertussis vaccine was the only pertussis vaccine licensed by the Food and Drug Administration (FDA) for use in the United States. It remains the only licensed vaccine today.

The whole cell pertussis vaccine is neurotoxic and can cause adverse reactions. These reactions are of two types: local and severe. Local reactions include swelling, fever, irritability, and crying spells. Severe reactions include encephalopathy, paralysis, and even death. The expected rate of severe reactions ranges between one in 100,000 and one in 310,000 doses. Prior to this incident, there had been only one case of transverse myelitis reported in connection with a DPT vaccine.

During the 1950's the Eli Lilly Company developed a fractionated cell pertussis vaccine called Tri-Solgen that was prepared by treating whole killed pertussis cells with salt. Early studies indicated that this method of preparation resulted in a less toxic vaccine, and following its approval by the FDA in 1967, Tri-Solgen occupied a substantial share of the market. Lilly withdrew from the vaccine business in 1975 and stopped producing Tri-Solgen. Lilly sold the right to produce Tri-Solgen to Wyeth Laboratories; however, the FDA has refused to relicense the vaccine.[1]

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[1] At oral argument, Toner disputed this assessment of the record, asserting that the Court of Appeals failed to account for the cross-examination of a certain key witness (whom Toner did not identify).

Lederle was aware of the neurotoxicity of Tri-Immunol as early as the 1950's and since that time has received occasional reports of severe adverse reactions to the vaccine. Following FDA approval of Tri-Solgen, Lederle conducted an internal study comparing Tri-Immunol with Tri-Solgen in an effort to determine whether to develop its own fractionated cell product. The study found fewer local reactions associated with Tri-Solgen, but it noted no severe reactions in either cohort due to the restricted number of subjects studied. At trial, Dr. Frank Cano, the Manager of Biologics at Lederle, testified that the differences observed in the study lacked statistical significance. Lederle only experimented with the production of a fractionated cell product until 1975. Since then, Japan has developed a pertussis toxoid vaccine, and Lederle's research efforts to achieve that objective may reach fruition within the next few years.

The principal thrust of appellees' negligence argument at trial concerned Lederle's failure to develop a fractionated cell product. In support of this theory, appellees contend that Tri-Solgen was shown to be a safe yet equally efficacious pertussis vaccine. Appellees' experts testified that the whole cell vaccine was five times more reactive than the fractionated cell product, and that early studies indicated that Tri-Solgen caused fewer local reactions than the whole cell vaccine. The studies did not establish, however, that Tri-Solgen caused fewer severe reactions than the whole cell vaccine.[2] With regard to efficacy, appellees produced four studies that found that fractionated cell products produced an immune response to pertussis. However, in 1972, a review panel within the Bureau of Biologics of the FDA refused to certify Tri-Solgen as "safe and effective" although it did so certify the whole cell vaccines. Because the FDA has refused to relicense Tri-Solgen or any other fractionated

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[2] At oral argument, Toner claimed his experts testified that a fractionated cell vaccine would cause five times fewer catastrophic reactions.

cell product, the manufacture and sale of such a vaccine by Lederle, or any other pharmaceutical company, would constitute a criminal offense under the Food, Drug and Cosmetic Act. *See* 21 U.S.C. §§ 331(d), 333(a), 355(a) (1982). *Toner v. Lederle Laboratories*, 779 F.2d 1429, 1430-31 (9th Cir.1986) (footnotes added).

As noted, Toner vigorously disputes this characterization of the facts. Without the trial record (other than the proposed and given jury instructions) before us, we cannot make an independent assessment. However, until it is determined otherwise, we must presume that sufficient evidence supported the jury's verdict that Lederle was negligent. *See Glovatorium, v. N.C.R. Corp.*, 684 F.2d 658, 660 (9th Cir.1982) ("This court will not disturb a jury verdict unless the evidence is such 'that no reasonable [person] would accept it as adequate to establish the existence of each fact essential to the liability.' *Kunz v. Utah Power & Light Co.*, 526 F.2d 500, 504 (9th Cir.1975)....").

By examining the allegations, the jury instructions, and the jury verdicts, we can further narrow that which we must presume. Lederle's standard of care relevant to the allegations of negligence was most specifically addressed in the following jury instruction, requested by Lederle and given by the trial court:

> INSTRUCTION NO. 27: A manufacturer of vaccines has the duty to exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products. The failure to meet this standard of due care in light of all the attendant circumstances will constitute negligence and subject the manufacturer to liability for the resulting consequences. The fact that the consumer's injuries were proximately caused by the manufacturer's product does not in and of itself constitute a sufficient basis upon which to predicate the manufacturer's liability. When the

> cause of action sounds in negligence, a manufacturer's duty to additionally test and investigate the propensities of its product is dependent upon the foreseeable risk of harm to potential users in light of then current scientific or medical knowledge and discoveries. R., Vol. II, p. 90, *quoted in Toner, supra*, 779 F.2d at 1431-32.

Toner specifically alleged "[t]hat Lederle was negligent in manufacturing and/or marketing the vaccine." R., Vol. 2, p. 85 (Jury Instruction No. 18). As we understand it, the thrust of Toner's case was not that the whole cell vaccine itself could have been more safely designed, but that Lederle knew of a safer alternative design—the fractionated cell vaccine—but failed to develop it and seek FDA certification of it. Toner alleged that Lederle could have marketed the safer alternative, but negligently failed to do so.

The jury returned the following verdict:

> QUESTION NO. 2: Was defendant Lederle Laboratories negligent in connection with the product Tri-Immunol which was the proximate cause of the plaintiff's injuries? Yes. *Toner, supra*, 779 F.2d at 1433.

Taking the jury instructions, the allegations, and the jury verdict together, we conclude the jury found that "in light of all the attendant circumstances," Lederle failed "to exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products," R., Vol. 2, p. 90 (Jury Instruction No. 27), that "the foreseeable risk of harm to potential users in light of then current scientific or medical knowledge and discoveries" was such that Lederle was negligent in failing to further "test and investigate the propensities of its product" relative to those of the allegedly safer product, *id.*, and that as a result Lederle was negligent for having "manufactur[ed] and/or market[ed] the [whole cell] vaccine" rather than the alternative. R., Vol. 2, p. 85 (Jury Instruction No. 18).

Certain factual presumptions also flow from the instructions, allegations, and verdict on the strict liability claim. The jury was instructed as follows:

> INSTRUCTION NO. 21: A product is in a defective condition, unreasonably dangerous to persons if it is more dangerous than would be expected by an ordinary person who may reasonably be expected to use it. The law does not say what would be expected by an ordinary person or who may reasonably be expected to use the product. Both of these issues are for you to decide. R., Vol. 2, p. 87.

The jury received no instruction based on comment k of Restatement (Second) of Torts § 402A (1965).

Toner alleged "[t]hat at the time the vaccine was manufactured it was defective, in that it subjected the users to an unnecessary risk of serious harm or death." R., Vol. 2, p. 85 (Jury Instruction No. 18). However, the jury returned the following verdict:

> QUESTION NO. 3: Was the product Tri-Immunol manufactured by the defendant Lederle Laboratories in a defective condition unreasonably dangerous to persons which was the proximate cause of the plaintiffs' injuries? No. *Toner, supra*, 779 F.2d at 1433.

Taking the instructions, arguments, and verdict together, we conclude that the jury found the vaccine not to be "in a defective condition unreasonably dangerous to persons. . . ." *Id.* Nothing in the record before us indicates that either the jury or the trial court made any determination based on comment k.[3]

We undertook the above exercise in order to understand the jury's determinations in relation to the certi-

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[3] However, the jury's apparent finding that there existed a safer alternative to the whole cell vaccine equates with a determination that the vaccine was not unavoidably unsafe, as will be explained *infra*.

fied questions, and to put our answers to those questions in perspective.[4] As will become clear, the posture of this case dictates the extent of detail of our answers.

II. THE CERTIFIED QUESTIONS

The Court of Appeals posed the two questions which we accepted as follows:

> (1) Under Idaho law, do the principles set forth in *Restatement (Second) of Torts* § 402A comment k apply to strict liability and negligence claims, and in particular to the claims in this suit?
>
> . . . .
>
> (4) Were the jury instructions on the issue of negligence in full accordance with Idaho law, given the contentions of the parties in this case? *Toner, supra,* 779 F.2d at 1433.

However, the Court of Appeals invited us to "reformulate the relevant state law questions as [we] perceive[] them to be. . . ." *Id.* Upon consideration, we find such reformulation necessary.

The first certified question in reality is two: do the principles of comment k apply to strict liability claims,

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[4] More specifically, we were obliged to make these determinations by the certified questions. The Court of Appeals asked us to decide its questions on comment k in the context of the claims and contentions in this case. Thus, we found it necessary to determine whether comment k had been applied at the trial court level before determining whether it could be applied to this case. We also found it necessary to determine if any trial court findings bore on the application of comment k to the claims and contentions of this case. As explained *infra,* there is no occasion for us to decide whether comment k applies to the vaccine at issue, since (1) the jury's determination on negligence would appear to conflict with such a holding, *see* note 3, *supra,* (2) the trial court gave no instruction and made no determination as to the application of comment k, (3) Lederle prevailed against the strict liability claim, to which comment k provides a defense, and (4) the application of comment k is a question mixing law and fact which requires an evidentiary hearing.

and do they apply to negligence claims. We will address the first part of the first question separately.

The second question (numbered (4) above) appears to directly relate to the latter part of the first question, particularly in light of the Court of Appeals' following discussion:

> Appellant argues that the instruction [No. 27, quoted *supra*] is insufficient because it does not recognize that certain drugs have unavoidable risks but must, nevertheless, be used to protect the public health. To support its argument, appellant cites *Restatement (Second) of Torts* § 402A comment k (1965), which recognizes that the marketing of some drugs is fully justified to prevent disease despite risks inherent in their use. As appellant recognizes, the *Restatement* section and its comment pertain to strict liability; but, appellant argues, the controlling principles are also applicable to the question of liability for negligence.
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> Though appellees contend that the issue in this case is not the applicability of comment k but, rather, the appellant's alleged negligence in failing to develop a fractionated cell vaccine, we see the questions as related. The concept of an unavoidably unsafe product seems necessarily to depend on whether research was properly pursued. If this is true, the trial court may have omitted a material element of negligence in failing to instruct the jury to decide whether Tri-Immunol was an unavoidably unsafe product. *Id.* at 1432.

The negligence instructions would seem to present no difficulties to the Court of Appeals, except in relation to Lederle's argument concerning comment k. The Court of Appeals apparently wishes this Court to determine both (1) whether the principles of comment k apply to negligence claims, (as stated in the latter part of the first question), and if they do apply, (2) whether the above

quoted negligence instruction (or any other of the given negligence instructions) sufficiently incorporates those principles.

Accordingly, we reformulate the certified questions as follows:

(1) Under Idaho law, do the principles set forth in Restatement (Second) of Torts § 402A comment k (1965) apply to strict liability claims, and in particular to the claim in this suit?

(2) (a) Under Idaho law, do the principles set forth in Restatement (Second) of Torts § 402A comment k (1965) apply to negligence claims, and in particular to the claim in this suit? [5]

(b) If the above question no. (2) (a) is answered affirmatively, did the trial court's instructions on negligence sufficiently incorporate those principles?

III. QUESTION 1

We turn first to the question of whether the principles set forth in Restatement (Second) of Torts § 402A com-

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[5] Contrary to Toner's assertion, this question does not equate to "[w]hether the Toners had to prove that Tri-Immunol was unreasonably dangerous to prevail on their negligence claim." Appellants' Brief, p. 7. Unreasonable dangerousness, as used in this context, is an element of a strict liability cause of action, not of a negligence cause of action. There is no dispute that negligence and strict liability are separate, non-mutually exclusive theories of recovery, and that "[the] failure to prove one theory does not preclude proving another theory." *Chancler v. American Hardware Mutual Insurance Co.*, 109 Idaho 841, 846, 712 P.2d 542, 547 (1986). As the Washington Supreme Court stated: "Negligence and strict liability are not mutually exclusive because they differ in focus: negligence focuses upon the conduct of the manufacturer while strict liability focuses upon the product and the consumer's expectation." *David v. Globe Machine Manufacturing Co., Inc.*, 102 Wash.2d 68, 684 P.2d 692, 696 (1984), *cited in Chancler, supra*, 109 Idaho at 846, 712 P.2d at 547. The Court of Appeals' question concerns not the relationship between negligence and strict liability, but on the relationship between negligence and a *defense to* strict liability, *i.e.*, the "unavoidably unsafe" product doctrine.

ment k apply to strict liability claims, and in particular to the claim in this suit. Our treatment of the question, however, will be general only. As best we can determine, the Court of Appeals poses the question for contextual purposes only. Nevertheless, we will examine comment k closely before venturing to adopt it or reject it.

Our belief that the Court of Appeals poses the question for contextual purposes only is based on our understanding that the issue the question involves is not before the court on appeal. Comment k provides an exception to strict liability for products deemed "unavoidably unsafe." Essentially, then, comment k is a defense to strict liability claims against products. In the instant case, the jury found the vaccine was not "in a defective condition unreasonably dangerous to persons which was the proximate cause of the plaintiff's injuries." *Toner, supra*, 779 F.2d at 1433 (quoting from the jury verdict). In other words, as the Court of appeals noted, "the jury rejected the strict liability . . . claim[]. . . . *Id.* at 1430. The Toners do not appeal from that verdict. The viability of a defense to a claim, where the claim failed, and where the plaintiffs do not appeal, would not seem to be an issue on appeal.

The crux of Lederle's appeal involves whether the principles of comment k apply to a negligence claim—the claim upon which the jury found for the Toners. Comment k is a provision of Restatement (Second) of Torts § 402A (1965). Section 402A concerns claims based on the strict liability of sellers of products, and not claims based on negligence. The Court of Appeals may have thought it unlikely that this Court would apply the principles of comment k to a negligence claim without first determining that they apply to the strict liability claims for which the comment was designed. We will proceed with that understanding.

This Court adopted Restatement (Second) of Torts § 402A (1965) concerning the strict liability of sellers

of products, of which comment k is a part, in *Shields v. Morton Chemical Co.*, 95 Idaho 674, 676-77, 518 P.2d 857, 859-60 (1974). Subsequently, this Court has consistently adhered to § 402A and often to its accompanying comments. *See, e.g., Rojas v. Lindsay Manufacturing Co.*, 108 Idaho 590, 592, 701 P.2d 210, 212 (1985) (applying comments i and l); *Fish Breeders of Idaho, Inc. v. Rangen, Inc.*, 108 Idaho 379, 391 n. 3, 700 P.2d 1, 13 n. 3 (1985) (applying comments g, h, and j); *Lasselle v. Special Products Co.*, 106 Idaho 170, 172, 677 P.2d 483, 485 (1984) (applying comment n); *Farmer v. International Harvester Co.*, 97 Idaho 742, 747, 749, 553 P.2d 1306, 1311, 1313 (1976) (applying comment i); *Mico Mobile Sales & Leasing, Inc. v. Skyline Corp.*, 97 Idaho 408, 414, 546 P.2d 54, 60 (1975) (applying comment h); *Rindlisbaker v. Wilson*, 95 Idaho 752, 759-60, 519 P.2d 421, 428-29 (1974) (applying comments h and n). To date, a case implicating comment k has not presented itself.

In its entirety, comment k reads:

> *k. Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this reason cannot legally be sold except to physicians or under the prescription of a physician. It

> is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk. (Emphasis original).

Comment k establishes an exception to the test for strict product liability. That test as set out in § 402A imposes liability on "[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his [or her] property . . .," § 402A(1), whether or not "the seller has exercised all possible care in the preparation and sale of his product. . . ." § 402A (2)(a). Comment g defines "defective condition" as "a condition not contemplated by the ultimate consumer which will be unreasonably dangerous to him [or her]." Comment k, however, defines a category of "unavoidably unsafe" products which, "when properly prepared, and accompanied by proper directions and warning, [are] not defective, nor . . . *unreasonably* dangerous." (Emphasis original). To leave no doubt, comment k restates the proposition: "The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is *not to be held to strict liability* for unfortunate consequences attending their use. . . ." (Emphasis added.) Thus, if a product qualifies as "unavoid-

ably unsafe," the seller is held not to the strict liability standard, but only to the standard of negligence.[6]

As precondition to its application, comment k requires that the product be "properly prepared, and accompanied by proper directions and warning. . . ." Generally speaking, there are three varieties of product defects: manufacturing flaws, design defects, and inadequate warnings. *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374, 385 (1984). By its terms, comment k excepts unavoidably unsafe products from strict liability only where the plaintiff alleges a design defect, and not where the plaintiff alleges a manufacturing flaw or an inadequate warning.[7] Comment k intends to shield from strict liability products which cannot be designed more safely; however, if such products are mismanufactured or unaccompanied by adequate warnings, then the seller may be liable even if the plaintiff cannot establish the seller's negligence. Courts and commentators universally agree to this limitation on comment k's grant of immunity from strict liability. *See Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 657 (1st Cir.1981); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir.), *cert. denied*, 419 U.S. 1096, 95 S.Ct. 1096, 42 L.Ed.2d 688 (1974); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 128-29 (9th Cir.1968); *Yarrow v. Sterling Drug, Inc.*, 263 F.

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[6] In the next section, we will discuss further our conclusion that comment k immunity extends in a literal sense only to strict liability claims, and not to negligence claims. Our observation is no semantic distraction or confusion, as Justice Bakes states, but rather is based on the express language of comment k and on unanimous authority.

[7] However, as we recently stated: "[T]here generally is little difference in the requirements and analysis of the duty to warn under either a negligence or strict liability theory. . . . *See Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374, 386 (1984) and cases cited therein; *see generally* J. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss.L.J. 825, 842 (1973)." *Sliman v. Aluminum Company of America*, 112 Idaho 277, 280, 731 P.2d 1267, 1270 (1986) (footnote omitted).

Supp. 159, 163 (Dist.S.D.1967), *aff'd*, 408 F.2d 978 (8th Cir.1969); *Kearl v. Lederle Laboratories*, 172 Cal.App. 3d 812, 218 Cal.Rptr., 453, 465 [(Div. 4] 1985); *Feldman, supra*, 479 A.2d at 384; V. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K*, 42 Wash. & Lee L.Rev. 1139, 1141 (1985); S. Willig, *The Comment k Character: A Conceptual Barrier to Strict Liability*, 29 Mercer L.Rev. 545, 546, 575 (1978).

Having met these preconditions, a seller next must establish that the product's risk is in fact "unavoidable." Comment k states: "There are some products which, in the present state of human knowledge, are *quite incapable* of being made safe for their intended and ordinary use." (Emphasis added.); *see also, e.g., Belle Bonfils Memorial Blood Bank v. Hansen*, 665 P.2d 118, 122 (Colo.1983) ("[T]he risk must be unavoidable under the present state of knowledge."). Obviously, for this to be true, the design must be safe as the best available testing and research permits. Schwartz, *supra*, 42 Wash. & Lee L. Rev. at 1141.

As an additional element of an "unavoidable risk," there must be, at the time of the subject products distribution, no feasible alternative design which on balance accomplishes the subject product's purpose with a lesser risk. *See Kearl, supra*, 218 Cal.Rptr. at 464; *Belle Bonfils, supra*, 665 P.2d at 123; Prosser and Keeton, *The Law of Torts* § 99, p. 700 (5th ed. 1984). If there were, then the risk would not be "unavoidable" or "apparently reasonable." Nor would the "marketing and use of the [product] be fully justified" if there were such an alternative design. Consequently, comment k by definition would not apply. The evaluation of a purported alternative design and the subject product's design should consider the magnitude of the subject product's risk that the alternative avoids, the financial costs of the compared designs, the benefits of the compared designs, and the relative safety of the compared designs, including any new risk that the

alternative would pose. *See Kearl, supra*, 218 Cal.Rptr. at 464, *Belle Bonfils, supra*, 665 P.2d at 123; Prosser and Keeton, *supra*, § 99, p. 100.

Where their risks are unavoidable, comment k shields from strict liability those sellers who "supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." As examples of such products the comment cites (1) the Pasteur treatment of rabies, which averts "a dreadful death" while "not uncommonly lead[ing] to very serious and damaging consequences when it is injected," and (2) "new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk." Clearly, the comment contemplates a weighing of the benefit of the product against its risk. Obviously, for comment k to apply, the benefit must outweigh the risk. This weighing process should consider the value of the benefit, the seriousness of the risk, and the likelihood of both. *Belle Bonfils, supra*, 665 P.2d at 122; *Kearle, supra*, 718 Cal. Rptr. at 464. We agree with Professor Sidney Willig that "[i]t does not serve society that an unavoidably unsafe product, which has occasional or fractious benefit, should enjoy insulation from strict liability in tort when the product's predominant effects are detrimental to individual and public safety." Willig, *supra*, 29 Mercer L. Rev. at 545. Consequently, the scales must clearly tip in favor of the benefits for comment k to apply. *Cf. Brochu, supra*, 642 F.2d at 657 ("If, as Comment k explains, the danger is unavoidable and the utility is great, liability may be avoided with proper warning." (Footnote omitted)); *Belle Bonfils, supra*, 665 P.2d at 122 ("the product's utility must greatly outweigh the risk created by its use . . . ."); *Kearl, supra*, 218 Cal.Rptr. at 464 ("If the court concludes after taking such evidence that (1) the

product was intended to provide an exceptionally important benefit that made its availability highly desirable, (2) the risk posed by the product was substantial and unavoidable when distributed, and (3) the interest in availability, measured as of the time of distribution, outweighs the interest in promoting enhanced accountability, the product will be deemed unavoidably dangerous and exempted from strict products liability design defect analysis.")

The weighing must be done as of the time the product is distributed to the plaintiff. *Belle Bonfils, supra*, 665 P.2d at 122-23; *Kearl, supra*, 218 Cal.Rptr. at 464; *Cochran v. Brooke*, 243 Or. 89, 409 P.2d 904, 906 (1966). Comment k does not require sellers to be clairvoyant. When, a product is "*apparently* useful and desirable," (emphasis added), considering its benefits and risks, then it ought to be immune from strict liability. Such products can include new or experimental drugs for which "there can be no assurance of safety." Comment k only requires that the balance "*apparently*" tip toward the benefit of a product at the time of distribution. *Accord*, Schwartz, *supra*, 42 Wash. & Lee L.Rev. at 1144. No strict liability attaches if, contrary to the best available information, the risk later proves greater. In this manner, comment k removes a disincentive to "the development of *new* drugs that have the potential for conquering disease." *Id.* (emphasis original).

It follows that when the balance appears at the time of distribution to tip toward the benefit of a product, strict liability will not attach when an unexpected and unknown risk injures a user. *Id.* (see cases cited therein); *see also Singer v. Sterling Drug, Inc.*, 461 F.2d 288, 290 (7th Cir.), *cert. denied*, 409 U.S. 878, 93 S.Ct 131, 34 L.Ed.2d 132 (1972); 3 L. Frumer and M. Friedman, *Products Liability* § 33.02[4] (1983). Taken out of context, comment k's reference to a "known but apparently reasonable risk" can be read to extend its coverage to only known risks. *See Belle Bonfils, supra*, 665 P.2d at

123. However, by specifically including new and experimental drugs for which "there can be no assurance of safety," and other products whose benefits appear to outweigh their risks at the time of distribution, comment k clearly intends to guard against strict liability resulting from unknown risks as well as known risks. When comment k then refers to "a known but apparently reasonable risk," it refers not to specific side-effects or other hazards known at the time of distribution, but rather to what is known to be the over-all risk of the product, perhaps including the possibility of unknown side-effects or other hazards in addition to those already known. *Accord*, Schwartz, *supra*, 42 Wash. & Lee L.Rev. at 1144-45 (see cases cited therein); 3 Frumer and Friedman, *supra*, § 33.02[4]. Commentator Schwartz aptly observed:

> [A]s a practical matter, there is little difference in the terms of actual harm between a risk that was "apparently reasonable" and turned out not to be (for example, risk of slight impairment of vision was known but *blindness* resulted) and a totally unknowable risk. To differentiate between the known risk that turns out to be more serious and a totally new risk, which may indeed be a minor risk, does not square with the policy underlying comment k or for that matter with common sense. The only reasonable conclusion is that comment k includes products which contain risks that were not knowable at the time of manufacture. Schwartz, *supra*, 42 Wash. & Lee L. Rev. at 1145 (emphasis original).

While sellers need not be clairvoyant, they are held to the knowledge and experience of experts in their fields. *Feldman*, *supra*, 479 A.2d at 386-87; *Belle Bonfils*, *supra*, 665 P.2d at 126. Knowledge of the product's risks based on reliable and obtainable information is imputed to the seller. *Id.* Thus, the balancing between benefits and risks is based on the best available information at the time of distribution, not merely the information known to the seller.

Where the balancing results in the application of comment k's immunity from strict liability, the immunity is not perpetual. If new information later tips the balance toward the risk of a product, or if new developments make possible a safer design, at that point further distributions of the product are not protected by comment k. Says Schwartz: "The public policy of encouraging the production of new and hopefully efficacious drugs is not compromised by imposing a reasonable standard on manufacturers to be responsible for new developments and risks in drugs they have marketed." Schwartz, *supra*, 42 Wash. & Lee L.Rev. at 1147.

Finally, the seller has the burden to establish the application of comment k. *Belle Bonfils, supra*, 665 P.2d at 122-23. Thus, comment k is an affirmative defense to a claim based on strict liability.

To summarize, comment k immunizes certain products from strict liability claims based on an alleged defective design, though not from strict liability claims based on alleged defective manufacture or inadequate warning. The products comment k shields cannot be designed to be more safe at the time of distribution, but bestow benefits which clearly appear at the time of distribution to outweigh their concomitant risks. This seems to us to be a sensible system. It also serves important policy considerations, particularly in the area of ethical drug manufacture. Commentator Schwartz puts it simply: "Society wishes to encourage the manufacture of ethical drugs, and the research and development of new drugs. The imposition of strict liability would stifle these goals." Schwartz, *supra*, 42 Wash. & Lee L.Rev. at 1141. As the citations within our discussion above evince, comment k has been widely adopted. *See* also Restatement (Second) of Torts § 402A comment k Appendices; *but see Collins v. Eli Lilly Co.*, 116 Wis.2d 166, 342 N.W.2d 37, 52 (1984) (Rejects comment k as "too restrictive and, therefore, not commensurate with strict products liability law in Wisconsin."). We hold that comment k applies to

strict liability claims based on an alleged defective design of a product, where that product qualifies under the comment k test as set out above.

We do not believe comment k was intended to provide nor should it provide all ethical drugs with blanket immunity from strict liability design defect claims. The comment refers to "*some*" products which are unavoidably unsafe; the comment states such products are "especially *common* in the field of drugs;" the comment cites certain examples from that field deserving of its protection and notes that "[t]he same is true of *many* other drugs, vaccines, and the like . . . [and] of *many* new or experimental drugs. . . ." (Emphasis added.) Obviously, the comment does not apply to *all* drugs. Rather, the comment applies "when the situation calls for it," which is when the product is unavoidably unsafe, but is "an apparently useful and desirable product, attended with a known but apparently reasonable risk," or with an unknown risk which was not yet reasonably discoverable at the time of marketing. It is equally obvious that not all drugs are so perfectly designed that they cannot be made more pure or more safe, or that there are not safer, suitable alternatives; nor do the benefits of all drugs necessarily outweigh their risks. *Brochu, supra*, 642 F.2d at 655; *Singer, supra*, 461 F.2d at 290-91; *Flood v. Wyeth Laboratories, Inc.*, 183 Cal.App.3d 1272, 228 Cal. Rptr. 700, 702-03 ([Div. 5] 1986); *Kearl, supra*, 218 Cal.Rptr. 463-64; *Feldman, supra*, 479 A.2d at 380, 383; Schwartz, *supra*, Wash. & Lee L.Rev. at 1141.

In this case, as previously explained, we need not determine whether or not the vaccine at issue qualifies for comment k protection. In any event, it is not for a court sitting on appeal to make such a determination.[8] The determination would require a full evidentiary hearing

[8] The issue of whether the application of comment k is a question of pure law upon which a court on appeal may pass, or of mixed law and fact requiring a full evidentiary hearing, clearly is substantive in nature.

such as only a trial court can provide. *Flood, supra*, 228 Cal.Rptr. at 703 (involved DPT vaccine); *Kearle, supra*, 218 Cal.Rptr. at 463; *Feldman, supra*, 479 A.2d at 383-84.[9] Like the *Kearl* court,

> we are uncomfortable with the rather routine and mechanical fashion by which many appellate courts have concluded that certain products, particularly drugs, are entitled to such special treatment. Indeed, "[t]he statement that drugs are unavoidably [dangerous], and therefore within the protection of Comment k, has become almost tautological." (Comment, *supra*, 31 DePaul L.Rev. at 254.) 218 Cal.Rptr. at 463.

Courts must decide the applicability of comment k case-by-case, and only after taking evidence related to the various factors discussed above. *Id.* at 463-64; *Feldman, supra*, 479 A.2d at 383.[10] Courts on appeal may review

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[9] The instant case does not present this issue of whether the judge or the jury ought to determine the application of comment k to a particular product. Some courts and commentators, emphasizing the factual determinations necessary, leave it to the jury. *Ortho Pharmaceutical Corp. v. Heath*, 722 P.2d 410, 416 (Colo. 1986); Willig, *supra*, 29 Mercer L.Rev. at 579; W. Prosser, *The Law of Torts* § 99, p. 662 (4th ed. 1971) ("When any evidence can be produced that [the risk] might have been avoided, [strict liability] becomes a question for the jury, and may lead to liability." (Footnote omitted.)) Others, concerned with the policy implications of the decision, would have the court decide comment k's application as a matter of law. *Johnson v. American Cyanamid Co.*, 239 Kan. 279, 718 P.2d 1318, 1323-24 (1986); Schwartz, *supra*, 42 Wash. & Lee L.Rev. at 1147-48; Wade, *supra*, 44 Miss.L.J. at 838, 844.

Either way, the decision of the applicability of comment k pertains only to claims based on defective design, and not to those based on defective manufacture or inadequate warning. The latter two raise questions of fact to be decided by the jury. *Sliman, supra*, 112 Idaho at 281, 731 P.2d at 1271 (on adequacy of warning); *Farmer v. International Harvester Co.*, 97 Idaho 742, 748-49, 553 P.2d 1306, 1312-13 (1976) (on defective manufacture).

[10] The criticisms of this aspect of *Kearl* to be found in *Brown v. Superior Court*, 182 Cal. App.3d 1125, 227 Cal.Rptr. 768 (1st Dist. [Div. 3] 1986), *review pending* are singularly unpersuasive. The

the finding below; "it is not [their] proper role, however, to assume or take judicial notice of facts sufficient to support such a finding." *Kearl, supra,* 218 Cal.Rptr. at 464.

Brown court's own approach is unclear, but it appears to advocate blanket immunity from strict liability for all prescription drugs rather than require any showing that comment k applies. *Id.* at 772, 774. As we explained above, such a rule runs counter both to the express language of comment k and to common sense. *Brown* provides no explanation for granting such immunity to all drugs.

The *Brown* court faults *Kearl* for leaving the questions related to comment k's applicability to the judge when "a trier of fact could determine the existence of risks and benefits." *Id.* at 774. This is an argument for the jury to make the determination, not for a court on appeal to arbitrarily declare all prescription drugs "unavoidably unsafe" as defined in comment k.

The *Brown* court asserts that "[t]he *Kearl* court failed to articulate standards for how these interests [which *Kearl* found relevant to whether comment k ought to apply] would be balanced by the trial court." *Id.* To the contrary, *Kearl* carefully defines the elements of its three-part test, particularly the requirements that a risk be "substantial" and "unavoidable" in order to guide the trial court's assessment of whether "the interest in availability . . . outweighs the interest in promoting enhanced accountability through strict liability." *Kearl, supra,* 218 Cal.Rptr. at 464. It is at least inadvisable if not impossible to provide some exact standard for comparing risks and benefits; nevertheless, it is far better to pose the correct questions raised by comment k itself, as does *Kearl,* than to merely attach indiscriminant and *carte blanche* immunity to all drugs as *Brown* seems to do.

Brown decries the possibility of trial courts inconsistently applying comment k to the same drug. In the process, *Brown* ignores its own observation that "at the review stage the appellate courts would harmonize the cases and establish legal guidelines satisfying the *Kearl* objective." 227 Cal.Rptr. at 775.

Finally, in contradiction to its earlier intimations that all prescription drugs ought to be immune from strict liability claims based on defective design, the *Brown* court appears to advocate "appellate courts [rather than trial courts] ruling as a matter of law that particular drugs are immune. . . ." *Id.* at 775. *Brown* fails to explain, nor can we imagine, just how an appellate court would make such a determination without hearing evidence and without a record developed below. *Kearl* correctly notes, "it is not our proper role . . . to assume or take judicial notice of facts sufficient to support such a finding." *Kearl, supra,* 218 Cal.Rptr. at 464.

IV. QUESTION NO. 2(a)

Question 2(a) asks: Under Idaho law, do the principles set forth in Restatement (Second) of Torts § 402A comment k (1965) apply to negligence claims, and in particular to the claim in this suit?

In a literal sense, comment k, when applicable, quite clearly does not act as a bar to negligence claims. By its own terms, the comment only bars claims that the product's design was "defective" and "*unreasonably* dangerous" (emphasis original)—in other words, strict liability claims. The comment expressly states that the seller of "unavoidably unsafe" products "is not to be held to strict liability for unfortunate consequences attending their use . . . ." The authorities universally agree that where a product is deemed unavoidably unsafe, the plaintiff is deprived of the advantage of a strict liability cause of action, but may proceed under a negligence cause of action. *E.g., Johnson v. American Cyanamid Co.*, 239 Kan. 279, 718 P.2d 1318, 1319 (1986); *Kearl, supra*, 218 Cal. Rptr. at 465; *Feldman, supra*, 479 A.2d at 381; *Stone v. Smith, Kline & French Laboratories*, 447 So.2d 1301, 1303 (Ala.1984); Schwartz, *supra*, 42 Wash. & Lee L. Rev. at 1139-41; 3 Frumer and Friedman, *supra*, § 33.02 (4], p. 328; Prosser, *supra*, § 99, p. 661.

By denying plaintiffs recovery based on the dangerousness of the product and requiring plaintiffs to prove negligent conduct on the part of the defendants, comment k furthers the policy of encouraging the production and marketing of useful products. Schwartz, *supra*, 42 Wash. & Lee L.Rev. at 1144. However, to immunize sellers of products deemed unavoidably unsafe pursuant to comment k from negligence claims would remove needed incentive for safe design. *Id.* at 1141; 3 Frumer and Friedman, *supra*, § 33.02[4]; p. 328.2. In the process of arguing that comment k covers unknown as well as known risks, Schwartz illustrates the balance comment k achieves between encouraging development and promoting

safety—a balance which would topple were there no action in negligence:

> Applying comment k to drugs that contain risks that were unknown at the time of manufacture simply keeps these drugs within the ambit of negligence law. Under negligence law, the pharmaceutical company is held to the very *highest* of standards. The pharmaceutical company must act as a reasonable person would have acted in the same or similar circumstances. The circumstances in which pharmaceutical manufacturers must deal directly involve severe risks to human life. Thus, their standard of care is not the "reasonableness" of a person who repairs a television set or drives a car—it is the most serious and intense obligation that one can find in the entire body of negligence law. To go beyond this, and require manufacturers to be responsible for the unknown (that is, to impose absolute or strict liability), flies in the face of the overall policy underlying the section. Schwartz, *supra*, 42 Wash. & Lee L.Rev. at 1144-45 (emphasis original) (footnotes omitted).

Professor Willig aptly concludes:

> If plaintiff cannot adduce evidence to prove that the product was defective, improperly prepared or unaccompanied by proper direction and warning, § 402A should not be available; but unlikely as it might sound, plaintiff should not be precluded in essaying a cause of action in negligence. *Willig, supra*, 29 Mercer L.Rev. at 546 (footnote omitted).

Thus, when comment k applies, the plaintiff still may allege negligence. Further, even if the application of comment k is a question for the judge (*see supra*, n. 7), the determination of negligence remains for the jury.[11]

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[11] By this, we mean the determination of whether there has been a breach of duty. As shown, *infra*, balancing risk against utility tests whether the conduct was unreasonable and thus a breach of duty. *See* W. Prosser, *The Law of Torts* §§ 31 and 37, pp. 148-49 (4th ed. 1971).

In a general sense, however, the comment k concerns and its required balancing between risks and benfits are similar to those involved in a negligence claim. As the Restatement notes, for an act to be unreasonable and thus a breach of duty under negligence analysis, the risk must be "of such magnitude as to outweigh what the law regards as the utility of the act or of the particular manner in which it is done." Restatement (Second) of Torts § 291 (1965); *see also Brizendine v. Nampa-Meridian Irrigation Dist.*, 97 Idaho 580, 586, 548 P.2d 80, 86 (1976) ("'[I]n negligence cases, the duty is always the same, to conform to the legal standard of reasonable conduct in the light of the apparent risk.'" *Quoting* Prosser, *supra*, § 53, p. 324); *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947). Comment k requires a similar weighing. Under negligence analysis, the utility of the act depends upon the value of the interest advanced, the extent to which it is advanced, and the opportunity for a less dangerous course of conduct, Restatement (Second) of Torts § 292 (1965), just as comment k's application depends on the value of the product's benefit, the extent to which the benefit accrues, and the availability of a feasible alternative design. The risks too are similarly considered by comment k and negligence law. *See* Restatement (Second) of Torts § 293 (1965). Such a weighing is implicit in the duty to use due care to avoid injuries while rendering services. *Stephens v. Stearns*, 106 Idaho 249, 257, 678 P.2d 41, 49 (1984). In sum, the determination under comment k that the design of a product is unavoidably unsafe and yet affords benefits outweighing its risks varies little from the determination under negligence law that the designing and marketing of the product was reasonably done. *Cf. Feldman, supra*, 479 A.2d at 385-86 ("'Since proper design is a matter of reasonable fitness, the strict liability adds little or nothing to negligence on the part of the manufacturer * * *.' *W. Prosser, Law of Torts* 659 n. 72 (4th ed. 1971."); Willig, *supra*, 29 Mercer L.Rev. at 54[illegible] ("In terms of negligence liability, an un-

avoidability unsafe product with high benefit potential certainly may overcome an argument that its sponsor is derelict in duty, provided that its design or formulation, its instructions as to use, and its warnings as to dangers are reflective of the present state of human skill, knowledge and maker expertise."); Wade, *supra*, 44 Miss.L.J. at 841 ("There is little difference here [in cases of improper design] between the negligence action and the action for strict liability." (Footnote omitted.)).

We conclude that the principles of comment k do not literally apply to negligence claims. More specifically, comment k does not shield sellers of products from negligence claims. On the other hand, in a general sense, the principles of comment k relate to the negligence concepts as expressed in Restatement §§ 291-93. However, the question of negligence remains for the jury to decide.[12]

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[12] Lederle and *amicus* argue that FDA certification ought to constitute non-negligence *per se*, even though to our knowledge Lederle did not request an instruction to that effect. The weight of authority and reason dictate otherwise. FDA certification represents only the FDA's opinion, albeit an informed one, of the safety and efficacy of the drug. Regrettably, drugs occasionally prove not so safe as the FDA first believed. *See, e.g., Singer, supra*, 461 F.2d at 290-91 (Certified drug Aralen proves to cause blindness.); *Feldman, supra*, 479 A.2d at 378-79, 392 (Studies showed tetracycline stained teeth well in advance of FDA action to require warnings.); *Cudmore v. Richardson-Merrell, Inc.*, 398 S.W.2d 640 (Tex. 1965), *cert. denied*, 385 U.S. 1003, 87 S.Ct. 705, 17 L.Ed.2d 542 (1967) (Certified drug MER-29 proves to cause cataracts.). Despite the FDA's best efforts, negligently designed drugs may and aparently do sometimes reach the market. Nothing in federal statutory or regulatory law indicates that FDA certification intends to preclude allegations of negligence in these cases. *See MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65, 70-71 (1985); *Michael v. Warner/Chilcott*, 91 N.M. 651, 579 P.2d 183, 186 (App. 1978). We hold that FDA certification of a drug is evidence but not conclusive evidence of the drug manufacturer's reasonableness; the trier of fact may assign FDA approval the weight it deserves. *Accord, e.g., id.; Brochu, supra*, 642 F.2d at 658 (*see also* cases cited therein); *Feldman, supra*, 479 A.2d at 383; *Barson v.*

V. QUESTION 2(b)

In answer to question 2(b), we hold that the jury instructions on negligence, particularly Jury Instruction No. 27, quoted *supra*, p. 6, adequately incorporated many though not all the principles common to comment k and negligence law as discussed above.[13] Like comment k, Instruction No. 27 imposed on Lederle not the requirement of clairvoyance, but only the duty to act reasonably given "the foreseeable risk of harm to potential users in light of then current scientific or medical knowledge and discoveries." While the instruction did not explicitly establish a balancing between utility and risk, as we noted earlier, such a balancing is implicit in the instruction's requirement that the manufacturer "exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products." *See Stephens, supra*, 106 Idaho at 257, 678 P.2d at 49. Certainly the following admonition invited the jury to consider the benefits of the vaccine as well as its risks: "The failure to meet this standard of due care [not to expose the potential consumer to an unreasonable risk of harm] *in the light of all the attendant circumstances* will constitute negligence. . . ." R., Vol. II, p. 90 (Jury Instruction No. 27) (emphasis added). Further, the instruction clearly indicated that the fact the vaccine

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E.R. Squibb & Sons, Inc., 682 P.2d 832, 836 (Utah 1984); *Ferrigno v. Eli Lilly & Co.*, 175 N.J.Super. 551, 420 A.2d 1305, 1320 (1980); *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 528 P.2d 522, 534-35 (1974); *Stevens v. Parke Davis & Co.*, 9 Cal.3d 51, 107 Cal.Rptr. 45, 507 P.2d 653, 661 (1973); Willig, *supra*, 29 Mercer L.Rev. at 558, 563; Restatement (Second) of Torts § 288C (1965).

[13] We fail to see grounds for Lederle to appeal from these instructions, since Lederle itself requested Jury Instruction No. 27, and did not request an instruction directly applying comment k to Toner's negligence claim. Nevertheless, we will assume the Court of Appeals had reason to pose the question concerning negligence instructions. Of course, it is for the Court of Appeals to decide whether Lederle had grounds to appeal from the instructions.

caused Kevin's injury by itself did not justify a finding of negligence: "The fact that the consumer's injuries were proximately caused by the manufacturer's product does not in and of itself constitute a sufficient basis upon which to predicate the manufacturer's liability." *Id.* Thus instructed, the jury undoubtedly considered the state of scientific knowledge and the utility of the vaccine before assigning negligence. Apparently, the jury was convinced that Lederle was negligent for having manufactured and marketed the whole cell vaccine instead of a safer alternative. However, the negligence principles common to comment k and Restatement (Second) of Torts §§ 291-93 (1965) could have been stated more explicitly. Had Lederle requested an instruction based on Restatement (Second) of Torts §§ 291-93, such an instruction would have accurately reflected Idaho law.

VI CONCLUSION

We have answered the certified questions in accordance with Idaho law and with well established precepts of strict liability and negligence law. Our answers in part may disappoint Lederle and *amicus* Pharmaceutical Manufacturers Association. Both sought total immunity from both strict liability and negligence claims for sellers of drugs so long as those drugs satisfied the requirements of the FDA and comment k. Their arguments were based less on legal authority than on policy considerations. Even without the record before us, we are aware of society's critical need for the DPT vaccine. No doubt liability flowing from the occasional injuries inflicted by the vaccine acts as a disincentive to its manufacture. However, this Court is not equipped to decide as a matter of public health policy that the relative efficacy and safety of the whole cell vaccine is so well established and the plight of Lederle so dire that injured persons such as Kevin Toner should be denied any recourse. Faced with similar supplications, the California Court of Appeals, Second District, Division 5, observed:

> Wyeth is not alone in predicting that a DPT vaccine shortage will be caused by the suits brought against the manufacturers, because production will become unprofitable. (See Horn, *Vaccine Crisis Spurs Bills in Congress* (Summer 1985) 10 Litigation News 5.) If this should occur, we would expect the Legislature to intervene to prevent the resulting health crisis. This is a legislative function. *Flood, supra*, 228 Cal. Rptr. at 703.

The *Flood* court's expectation was not unrealistic. At the time of this writing, the United States Congress has passed and the President has signed a bill "that would establish a federal 'no fault' compensation program for children injured as a result of routine, required vaccinations. . . ." *The Idaho Statesman*, October 15, 1986. This approach radically revises tort law in order to simultaneously protect the interests of society, the drug industry, and innocent victims of the rare but catastrophic severe reactions. It is an approach quite within the capacity of the legislative branch of government, but quite beyond the capacity of the judicial branch.

Remanded to the Court of Appeals.

DONALDSON and HUNTLEY, JJ., concur.

HUNTLEY, Justice, concurring specially.

I concur in the majority opinion and write further to address two points.

POINT I: All who read this opinion and that of the 9th Circuit at 779 F.2d 1429, should be aware that Lederle and the Amicus Curiae Pharmaceutical Manufacturers Association, in seeking to engraft comment k into negligence law, are proposing something far more revolutionary in its effect that most would realize.

They seek by the device of engrafting comment k into negligence law to actually abolish negligence causes of

action in this field and substitute the Food and Drug Administration for the jury.

The parties and Amicus were all in agreement in their presentations to this Court that not one state as yet has ruled that comment k applies to negligence causes of action.

Perhaps the reason that no state has done so is that no state supreme court has yet become convinced that the FDA has either adequate staffing, expertise, or data base to warrant its being substituted for the judicial system.

The full implications of the Pharmaceutical Manufacturers proposal can be more fully realized upon consideration of the partial transcript of the oral argument before this court of attorney Robert Koontz, arguing for Lederle, attached hereto as Appendix A and the entire transcript of attorney Malcolm Wheeler, arguing for the Pharmaceutical Manufacturers Association, attached hereto as Appendix B.

I fear the day when any supreme court can be convinced that an agency such as the FDA, no matter how well-intentioned, can supplant the American judicial system.

POINT II: There are two statements in the 9th Circuit opinion which trouble me as running counter to FDA procedures as I understand them:

> Lilly sold the right to produce Tri-Solgem to Wyeth Laboratories; however, the FDA has refused to relicense the vaccine.
>
> . . . .
>
> However, in 1972, a review panel within the Bureau of Biologics of the FDA refused to certify Tri-Solgen as "safe and effective" although it did so certify the whole cell vaccines. Because the FDA has refused to relicense Tri-Solgen or any other fractionated cell product, the manufacture and sale of such a vaccine by Lederle, or any other pharma-

ceutical company, would constitute a criminal offense under the Food, Drug and Cosmetic Act. *See* 21 U.S.C. §§ 331(d), 333(a), 355(a) (1982).

The foregoing statements seem to suggest that the fractionated vaccine Tri-Solgen is *disapproved* by the FDA.

It is my understanding that the FDA does not license a medication in a "vacuum." That is, a medication is licensed only to a specific manufacturer presenting a specific product which has undergone specific testing, with adequate data having been presented to the FDA. The FDA does not, for example, issue generalized approval for anyone who wishes to manufacture a specific medication.

Thus, the fact that a fractionated cell vaccine is not now licensed does not mean it is disapproved—it merely means either that no manufacturer has sought and obtained approval or that, in the instance of the 1972 refusal by a review panel of the Bureau of Biologics, the application therein failed to make an adequate showing of safety or efficacy, which is not to say that another manufacturer could not have made a successful application.

BAKES, Justice, specially concurring in part:

I concur in the result reached by the majority opinion and but for the somewhat equivocal means by which the majority reaches its result I would have fully concurred in its opinion. I write only to clarify the analysis of the issues, as I view them, raised by the questions presented by the Ninth Circuit's certificate to this Court.

I.

Questions Not Presented

First, given some of the language in the majority opinion, it is necessary to identify those issues which are not

before this Court for its determination. I refer primarily to those issues concerning federal procedural law. It is at once clear that the Ninth Circuit desires only advice regarding matters of Idaho substantive law. Issues concerning procedure within the federal court system are necessarily for that court to determine. *Erie R.R. v. Tompkins*, 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188 (1938). Thus, we are not required, nor would it be proper for us, to determine whether Lederle has waived its right to challenge Jury Instruction No. 27. Therefore, I do not join in that portion of the majority opinion which intimates an opinion on that issue; specifically, I do join in the language found in footnote 13, *ante* at 342-343, 732 P.2d at 311-312. I likewise view the issue of whether the determination of the applicability of comment k to a given product is one of law or fact, and thus for the court or the jury to decide, is an issue for the federal court to decide. Certainly, the federal court has not requested us to give an opinion on that issue. Thus, it is not appropriate for this Court to say that "it is not for a court sitting on appeal to make such a determination." *Ante* at 339, 732 P.2d at 308. Consequently, I decline to join in language to the contrary found in the majority opinion. That language is pure *dicta* and in no way binding on the federal court.

Finally, no question is presented by the Ninth Circuit certificate which requires us to second-guess the jury's verdicts in this case. There is no need to engage in any presumptions as to the evidence adduced at trial or as to the findings of the jury. Therefore, I do not join in any of the majority's attempts at such presumptions.[1] The

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[1] Specifically, I do not join in the majority's presumption that "the jury found that 'in light of all the attendant circumstances,' Lederle failed 'to exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products,' . . . that 'the foreseeable risk of harm to potential users in light of then current scientific or medical knowledge and discoveries' was such that Lederle was negligent in failing to further 'test and investigate the propensities of its product'

Ninth Circuit expressly stated that any questions regarding evidence adduced at trial or regarding the sufficiency of such evidence to support the jury verdicts are matters for its resolution. *Toner v. Lederle Laboratories*, 779 F.2d 1429, 1431 (9th Cir.1986). Rightly so; they are, again, matters of federal procedural law and not of substantive state law. If the Ninth Circuit has inaccurately characterized the facts in its opinion to us, as the majority attributes to counsel for Toner, *ante* at 332, 732 P.2d at 301, then the Ninth Circuit is the proper forum to determine such matters. Again, any presumptions made by the majority regarding what Toner proved and what the jury found are entirely unwarranted. They are not required in order to adequately address the questions presented.

II.

Questions Presented

The Ninth Circuit certified the following four questions to this Court pursuant to I.A.R. 12.1(a).

> (1) Under Idaho law, do the principles set forth in *Restatement (Second) of Torts* § 402A comment k apply to strict liability and negligence claims, and in particular to the claims in this suit?
>
> (2) If yes, is there evidence from which a jury could find Tri-Immunol unavodiably unsafe?
>
> (3) Under Idaho law, could the jury, on this record, find the defendant negligent for failure to develop a fractionated cell vaccine, or for any other reason?

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relative to those of the allegedly safer product, . . . and that as a result Lederle was negligent for having 'manufactured and/or marketed the whole cell vaccine' rather than the alternative." Ante at 332, 732 P.2d at 301 (emphasis added). I specifically disagree with the majority's presumptions regarding the underscored material in the above quote.

> (4) Were the jury instructions on the issue of negligence in full accordance with Idaho law, given the contentions of the parties in this case?

As the majority opinion correctly states, we accepted certification of only two of the four questions, numbers (1) and (4).

Though phrased in terms regarding the applicability of comment k, it is clear that the Ninth Circuit desires to know the elements which must be established to state a cause of action in a products liability case under state substantive law. "[W]e must look to the substantive law of the State of Idaho to determine the elements of plaintiffs' cause of action." *Toner v. Lederle Laboratories*, 779 F.2d 1429, 1431 (9th Cir.1986). Faced with a claim of inconsistent jury verdicts[2] which, as stated by the Ninth Circuit is a matter for their resolution, the Court of Appeals essentially desires that we (1) set forth the distinction between the elements of a products liability action based on strict liability and one based on negligence; (2) determine the applicability of the "unavoidably unsafe" doctrine of comment k of the Restatement (Second) of Torts, § 402A, to both strict liability and negligence actions; and then (3) indicate whether the jury instructions given in this case adequatly set forth those elements. As stated by the Ninth Circuit, "The question whether the trial court instructed the jury in accordance with Idaho law necessarily precedes resolution of the inconsistency claim." *Id.* at 1434.

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[2] Lederle contends that the jury's answers to the following two questions on the special verdict form are inconsistent.

> "*QUESTION NO. 2*: Was defendant Lederle Laboratories negligent in connection with the product Tri-Immunol was the proximate cause of the plaintiff's injuries? Yes.
>
> "*QUESTION NO. 3*: Was the product Tri-Immunol manufactured by the defendant Lederle Laboratories in a defective condition unreasonably dangerous to persons which was the proximate cause of the plaintiff's injuries? No." *Toner v. Lederle Laboratories, supra*, 779 F.2d at 1433.

A.

Products Liability Based On Strict Liability in Tort

As noted by the majority opinion, this Court in *Shields v. Morton Chemical Co.*, 95 Idaho 674, 518 P.2d 857 (1974), "accepted the doctrine of strict liability in tort in products liability actions." *Id.* at 676, 518 P.2d at 859. The rule of strict liability we adopted was that set forth in the Restatement (Second) of Torts § 402A (1965). Under that rule a cause of action exists against a seller of a product if a plaintiff establishes that he suffered injury resulting from his proper use of the product which, though properly used, was "in a defective condition" such as rendered it "unreasonably dangerous" to the user or consumer.

The difficulty in applying the rule of strict liability set forth in § 402A usually surfaces in regard to the meaning to be given the phrase "in a defective condition unreasonably dangerous to the user or consumer." As the majority opinion notes, comment g to § 402A defines "defective condition" as "a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him." Comment i defines "unreasonably dangerous" as a danger "beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." In *Rojas v. Lindsay Mfg. Co.*, 108 Idaho 590, 701 P.2d 210 (1985), we approved the following definition of the phrase: "A product is in a defective condition unreasonably dangerous . . . if it is more dangerous than would be expected by an ordinary person who may reasonably be expected to use it. * * * *i.e.*, for whose use it must be safely designed." *Id.* at 591, 592, 701 P.2d at 211.

The definition of "in a defective condition unreasonably dangerous to the user or consumer" also takes on somewhat different meanings depending on the context of the products liability cause of action, *i.e.*, whether the

cause of action is premised on an alleged defect in the product's design, or in the product's manufacture (the design was not followed in the production phase), or in the product's warning concerning its known dangers. *See* W. Keeton, *Prosser and Keeton on The Law of Torts* § 99 (5th ed. 1984) (hereinafter *Prosser*). We need not fully discuss these different bases for strict liability and their concomitant definitions of "defective condition" since only the first is presented by this case. The heart of Toners' products liability claim is that a safer, more feasible alternative existed to Tri-Immunol. This claim relates solely to design defect.[3] As explained by the majority, comment k only applies, if at all, to design defect cases. *Ante* at 335, 732 P.2d at 304.

In a design defect products liability case, the effect of comment k is to modify the definition of when a product is "in a defective condition unreasonably dangerous" by stating that "there are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use * * *. Such a product, properly prepared, and accompanied by proper instructions and warning, *is not defective, nor is it unreasonably dangerous.*" Restatement § 402A (comment k). Thus, under comment k, if a product is "unavoidably unsafe," it is neither "defective" nor "unreasonably dangerous." Contrary to the majority opinion, comment k does not "immunize certain products from strict liability claims," *ante* at 339, 732 P.2d at 308, but merely defines which products are defective and unreasonably dangerous, and which are not. Thus, comment k clearly requires a utility-risk analysis, as the majority opinion concedes. The majority opinion acknowledges that comment k applies to actions for product liability based on strict liability in tort, although incorrectly describing the effect of comment k as resulting in an "immunity,"

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[3] As noted in the Ninth Circuit's opinion, Toners abandoned their allegations of defective warnings prior to submitting the case to the jury. *Toner v. Lederle Laboratories, supra,* 779 F.2d at 1430.

rather than merely acknowledging that unavoidably unsafe products are neither defective nor unreasonably dangerous.

B.

Products Liability Based on Negligence

While this Court has addressed strict products liability several times, as noted by the Ninth Circuit, we have never been presented with a case requiring a determination of "the duty, or standard of care, applicable to the manufacturer of drugs that are unsafe in some respects but that are necessary for the control of disease." *Toner v. Lederle Laboratories, supra*, 779 F.2d at 1432. Thus, we have never addressed the question of whether a product which is socially desirable or necessary, even though "unavoidably unsafe," may expose the manufacturer of that product to a products liability action whether on the theory of strict liability or negligence. On such a negligence claim, or upon any negligence claim for that matter, we have indicated that there are certain basic "concepts fundamental to any negligence action: duty, breach, proximate cause and damages," *Blake v. Cruz*, 108 Idaho 253, 257, 698 P.2d 315, 319 (1985). Or, as more accurately stated by Chief Justice Donaldson in *Alegria v. Payonyk*, 101 Idaho 617, 619 P.2d 135 (1980), cited by the Ninth Circuit Court of Appeals:

> "The elements of common law negligence have been summarized as (1) a duty *recognized by law*, requiring a defendant to conform to a certain standard of conduct; (2) a breach of that duty; (3) a causal connection between the defendant's conduct and the resulting injuries; and (4) actual loss or damage." *Alegria v. Payonk*, 101 Idaho 617, 619, 619 P.2d 135, 137 (1980) (emphasis added).

The majority opinion fails to adequately analyze the present case under these "concepts fundamental to any negligence action." Instead the majority simply states "the determination of negligence remains for the jury."

That statement is inadequate and to the extent it is inadequate, it is also misleading and incorrect.

The statement is correct only insofar as it applies to questions of fact. This Court has consistently held that if there is sufficient evidentiary support, all fact questions as to negligence are for the jury or trier of fact to decide. *O'Connor v. Meyer*, 66 Idaho 15, 154 P.2d 174 (1944). Questions of fact are usually raised in regard to elements (2), (3) and (4) above.[4] However, as both the quote and the holding in *Alegria* indicate, the question of "duty" is not for the jury, rather it is a question of law for the court to decide. Essentially, the question of the existence of a duty involves a legal determination that some relationship exists between the defendant and the plaintiff which gives rise to an obligation of conduct toward a partciular person in the first instance. "[D]uty is a question of whether the defendant is under any obligation for the benefit of a particular plaintiff." *Prosser* at § 53. "[W]hether the interest of the plaintiff which has suffered invasion was entitled to legal protection at the hands of the defendant . . . is entirely a question of law to be determined by reference to the body of statutes, rules, principles and precedents which make up the law; and it must be determined only by the court." *Id.* at § 37. The court is required to determine if, under the facts of a given case a duty is owed by defendant to plaintiff *and*, also, to determine the scope or extent of that duty.

> "The existence of 'duty' is a question of law. (Citations omitted.) 'Legal duties are not discoverable facts of nature, but merely conclusory expressions that, in cases of a particular type, liability should be

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[4] To the extent the majority opinion uses the term "negligence" to mean conduct contrary to that required by the duty owed by defendant to plaintiff, the term "negligent" essentially refers to element (2), *i.e.*, breach of duty. In such a context the assertion in the majority opinion that the determination of negligence is for the jury is correct since whether a defendant has breached his duty of care is a question of fact, not of law.

> imposed for damage.' *Tarasoff v. Regents of University of California*, [17 Cal.3d 425, 131 Cal.Rptr. 14, 551 P.2d 334 (Cal.1976).]" *Thompson v. County of Alameda*, 27 Cal.3d 741, 167 Cal.Rptr. 70, 614 P.2d 728, 732 (1980).

Furthermore, a determination of the existence of a duty in a particular case involves consideration of several factors, including:

> " 'the foreseeability of harm to the plaintiff, the degree of certainty that the plaintiff suffered injury, the closeness of the connection between the defendant's conduct and the injury suffered, the moral blame attached to the defendant's conduct, the policy of preventing future harm, the extent of the burden to the defendant and the consequences to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost, and prevalence of insurance for the risk involved.' " *Thompson v. County of Alameda*, 27 Cal. 3d 741, 167 Cal.Rptr. 70, 614 P.2d 728, 732-33 (1980) *quoting Rowland v. Christian*, 69 Cal.2d 108, 70 Cal.Rptr. 97, 443 P.2d 561, 564 (1968).

The analysis is the same in a products liability case. The question of duty involves a consideration or balancing of all of the above factors. "It is no part of the province of a jury to decide whether the manufacturer of goods is under any obligation for the safety of the ultimate consumer." *Prosser* at § 37.

As indicated in the majority opinion this balancing of risk versus utility in a negligence case is the same as that required in a strict liability case where comment k is deemed applicable. There is little difference between a products liability action in negligence and one in strict liability relating to the definition of the unsafe character of the product which allegedly causes the injury. In negligence law, and as the jury was instructed in Instruction 27 in this case, the product must not "expose the poten-

tial consumer to an unreasonable risk of harm." In strict liability, the product must not be in a "condition unreasonably dangerous to the user." The determination in negligence law of whether the product presents an "unreasonable risk of harm" to the consumer is really no different from the determination in strict liability law that a product is "unreasonably dangerous" to the consumer. The majority opinion acknowledges this, stating that there is, in reality, "little difference here [in cases of improper design] between the negligence action and the action based on strict liabilty."[5] *Ante* at 342, 732 P.2d at 311, *citing* W. Prosser, Law of Torts, 659, n. 72 (4th ed. 1971), *and quoting* Wade, On the Nature of Strict Tort Liability for Products, 44 Miss.L.J. 825, 841 (1973).

Since there is little or no difference between the negligence test of "unreasonable risk of harm" and the strict liability test of "unreasonably dangerous to the consumer," Comment k and its rationale applies to both products liability actions based on strict liability and those based on negligence. By definition, a product which is "unavoidably unsafe" is neither "unreasonably dangerous to the consumer" (the strict liability standard) nor does it create an "unreasonable risk of harm" to the consumer (the negligence standard).

Nevertheless, the majority states, *ante* at 342, 732 P.2d at 311. "We conclude that the principles of comment k do not literally apply to negligence claims. More specifically, comment k does not shield sellers of products from negligence claims." That statement exposes a misconception prevalent throughout the majority opinion that comment k "immunizes certain products from strict liability claims . . ." *ante* at 339, 732 P.2d at 308, and that "if a product

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[5] This conclusion reached by the majority opinion in Part IV negates the seemingly contrary assertion contained in footnote 6, *ante* at 336, 732 P.2d at 305. That footnote states, "In the next section, we will discuss further our conclusion that comment k immunity extends . . . only to strict liability claims, and not to negligence claims."

qualifies as 'unavoidably unsafe,' [under comment k] the seller is held not to the strict liability standard but only to the standard of negligence." *Ante* at 336, 732 P.2d at 305. Comment k is not an "immunity" or a "shield." Comment k merely limits the definition of defective products under Section 402A, excluding "unavoidably unsafe products" as being "not defective, nor . . . unreasonably dangerous." Therefore, the semantical distractions of "immunity" and "shields" employed in the majority opinion tend to confuse rather than enlighten its products liability analysis. Those terms distract the reader's attention from the fact that whether a particular products liability claim is phrased in terms of negligence or strict liability, there must either be a product which exposes the potential consumer to an "unreasonable risk of harm" (Negligence Instruction 27), or a product which is "unreasonably dangerous." Restatement (Second) § 402A. There is "little difference" between those two standards, as the majority opinion acknowledges. *Ante* at 342, 732 P.2d at 311.

C.

The Jury Instructions

Having hopefully helped explain the Court's decision regarding the elements of a cause of action for products liability based on strict liability and negligence, and the distinction between the two causes of action, the third question presented by the Ninth Circuit was whether the jury instructions given in this case adequately state the law in Idaho regarding a products liability action based on negligence. The majority's treatment of this issue is inadequate due in large part to its concern that Lederle should not be permitted to raise the issue. However, as noted earlier, any question regarding Lederle's ability to challenge the jury instructions is purely a question of federal law and not for this Court to decide. The question before this Court is not whether the *proposed* jury instructions adequately express Idaho law, but whether the instructions actually given by the trial court do.

The majority opinion correctly holds, though in a very equivocal manner, that the instructions given are *not* adequate statements of Idaho law on negligence given the facts as related by the Court of Appeals and the contentions of the parties in the present case. The instructions are entirely devoid of any reference to comment k's "unavoidably unsafe" standard or the requirement that the jury engage in a comment k risk *versus* utility balancing test. The majority asserts that the instructions implicitly required the jury to engage in such a balancing test. *Ante* at 342, 732 P.2d at 311. However, the majority opinion earlier concludes just the opposite, *ante* at 333, 732 P.2d at 302, when it states that, "*Nothing in the record before us indicates that either the jury or trial court made any determination based on comment k.*" Given that statement, I fail to see on what basis the majority opinion then asserts that "a balancing between utility and risk . . . is implicit in [Jury Instruction No. 27]." *Ante* at 343, 732 P.2d at 312. Furthermore, the majority's assertion that "the jury undoubtedly considered the state of scientific knowledge and the utility of the vaccine before assigning negligence," *ante* at 343, 732 P.2d at 312, is mere speculation at best.

Even assuming, *arguendo*, that the comment k test was implicit in the jury instructions and that the jury did in fact consider the utility of the vaccine and the state of scientific knowledge before assigning negligence, it is entirely inconsistent for the majority to then conclude, based on the jury's verdicts, "that Lederle was negligent for having manufactured and marketed the whole cell vaccine instead of a safer alternative." *Ante* at 343, 732 P.2d at 312. Such a conclusion is directly contrary to the jury's verdict that Tri-Immunol was not "in a defective condition unreasonably dangerous" to the consumer. In short, if the majority's assertion that neither the parties nor the trial court addressed comment k is true, then it is clear beyond cavil that the jury instructions did not adequately state the law of Idaho regarding negligence in a products liability case.

Conclusion

In conclusion, while the answers set out in the majority opinion to the two certified questions are less than clear, I believe the Court's opinion can ultimately be distilled down to the following responses.

As to question one, whether or not comment k applies to both strict liability and negligence claims in products liability actions, the answer is yes. The predicate for a products liability claim, whether based on negligence or strict liability, is a product which is "unreasonably dangerous," or which creates an "unreasonable risk of harm." Since there is little or no difference between those two standards, an "unavoidably unsafe" product whose utility outweighs the risk created by its use is by definition not "unreasonably dangerous" nor does it create an "unreasonable risk of harm."

As to the second question certified and adopted by this Court, *i.e.*, whether the jury instructions on the issue of negligence were in full accordance with Idaho law given the contention of the parties in this case, the Court's answer is an apparent no. The court's instructions did not instruct the jury regarding comment k's "unavoidably unsafe" standard and the risk *versus* utility balancing test contained therein.

What effect the answers to the certified questions have on the disposition of this case is a matter entirely for the federal courts to determine.

SHEPARD, C.J., concurs.

SHEPARD, Chief Judge, specially concurring in part:

I view the holding of the majority to be that comment k applies to negligence claims as well as claims based in strict liabiilty. I draw that conclusion from the language of the majority:

> [W]e conclude that the principles of comment k do not literally apply to negligence claims. More spe-

> cifically, comment k does not shield sellers of products from negligence claims. On the other hand, in a general sense, the *principles of comment k relate to the negligence concepts* as expressed in Restatement §§ 291-93. (emphasis added)

As to the remainder of the opinion, I concur in the special concurrence of BAKES, J.

[Appendix A to the Idaho Supreme Court Opinion]

Partial Oral Argument of Mr. Koontz
for Lederle Laboratories

JUSTICE HUNTLEY: Now, Mr. Koontz, for the reasons you and Justice Bakes have just discussed, I have to admit that as I read through the briefs my first inclination was that perhaps it would be desirable to engraft comment k on the negligence law, because we do need these ethical drugs. But when I try to take a step further and see what we're doing if we do it, and neither of you have gotten to it in the briefing, what is—what are you ultimately doing? Are you asking for us now—if we buy your program here, will we now in the future instruct the jury that a manufacturer may manufacture an unavoidably unsafe drug in a negligent and careless manner?

MR. KOONTZ: No.

JUSTICE HUNTLEY: What are—what do we have when we put comment k together with negligence? What will we tell the jury?

MR. KOONTZ: Well let—let me tell you, because, obviously, Justice Huntley I've—you know, thought about that long and hard. And you'll hear from the Pharmaceutical Manufacturers Association. And we—we talked about this in the 9th circuit. As a matter of fact the judge who had that case asked me almost that very—very same question. And I think with comment k this Court has the opportunity to engraft on comment k a rather limited exception. And that limited exception is this; that if medical science has only one product, i.e. the DPT vaccine, which is this case, there's no other licensed drug on the market. That given that set of circumstances, the Court as a matter of law must defer to the FDA, they must defer to the National Institute of Health, they must defer to the CDC and they must defer to the Bureau of Biologics in terms of study committees which are the people who make the policy for the United States.

JUSTICE HUNTLEY: Okay now. Okay, go ahead.

MR. KOONTZ: Let me just—I've only got . . .

JUSTICE HUNTLEY: Go ahead, finish. I've got to *follow* up . . .

MR. KOONTZ: . . . I'm saying that there is—that you can engraft on comment k a rather limited exception with the one vaccine. Now I'm excluding from that (inaudible) out the Johnson case, because Johnson there are two (inaudible). And I'm saying here in this case with the DPT vaccine, if you want to do that. I prefer the pharmaceutical manufacturers position that if you—if you find a social mandate to give a drug that—and I'm not talking about cosmetic drugs or anything like that. I'm talking about cancer drugs, DPT vaccine, Reubella, those kinds of things. That if the FDA approves those drugs you should limit it to warning and you should limit it to efficacy of manufacture, that it was made appropriately.

JUSTICE HUNTLEY: Okay now. You've focused me very well, and that's why—and getting me right to the problem I'm having. You framed that that the narrow rule would be that if there is only one product then we defer to the F—we tell the jury we defer to the FDA.

MR. KOONTZ: I'm simply saying, Justice Huntley, if you want to do that.

JUSTICE HUNTLEY: Okay. Okay now, I'm going to take . . .

MR. KOONTZ: If you want to really narrow the issue you can do it—you can do it that way.

JUSTICE HUNTLEY: I want to take you just one—one step at a time. Now, let's try that one. Now if we adopted that rule, you then would not foreclose a plaintiff from bringing a case saying there is a way to make another product and you're negligent in not doing it.

MR. KOONTZ: The answer to that is, Justice Huntley, that you give me the proposition in a products liability case and I'll find you an expert to testify to that fact. They're all trial lawyers and you'd—that's a fact

of life in our business. I'll give you somebody who will say, you could have made a better product. Now I think comment k is saying, no, you can't—you can't do that because where does it put the manufacturer? Because I'll tell you the next case. The next case is when you let a jury in Idaho reallocate American Cyanamid resources in R & D. They're big in the chemotherapy area. They're big in the (inaudible) cancer research area. Is our next case a cancer victim who says, well you developed a cure in—in, you know, in 1989, but you should have done it in '86 because . . .

JUSTICE HUNTLEY: Okay.

MR. KOONTZ: . . . you didn't allocate your resources right.

JUSTICE HUNTLEY: The short answer then is—is you're saying than that the rule of law would go one step further and it would say that there is no way to—in the circumstance we just described, that a party can bring an action on the basis of negligence in that a different or better product could have been made.

MR. KOONTZ: That's right.

JUSTICE HUNTLEY: So you would foreclose that type of action.

MR. KOONTZ: That's what comment k says.

JUSTICE HUNTLEY: Okay.

MR. KOONTZ: And that's what Dean Prosser discusses in great detail when that—and you have to understand that comment k is a national public health policy.

JUSTICE HUNTLEY: I understand that . . .

MR. KOONTZ: We're not talking about negligence or some—you know, a bunch of lawyers sitting around a table talking about strict liability and negligence. We're talking about a national public health policy.

JUSTICE HUNTLEY: Okay. I understand. I'm trying to have a conversation with you here so I can understand this. Now aren't we, if we applied comment k to this case and gave it the answer and the gloss that you've just discussed with me, don't we run into a little bit of a problem that, by definition the jury in having found

for the plaintiff on negligence in this case has to have found that there was a better way to build this mouse trap?

MR. KOONTZ: Well, I've got a couple of responses to that. First of all, this case was—I'm not sure of the year. Maybe Ken can—Ken can correct me. The vaccine was given in 1979, and we all live in a real world. It's 1986 and we don't see Tri-Solgen on the market today, and we don't see it in any country in the world. And what I'm saying is, Justice Huntley, that you cannot—and it's what the Johnson court said in determining that case on the Sabin vaccine. . . .

JUSTICE HUNTLEY: Well then you're saying the jury was wrong in what it found.

MR. KOONTZ: Well, it isn't that the jury's wrong.

JUSTICE HUNTELY: Well, they're either right or wrong.

MR. KOONTZ: I'm not arguing that—you know, that the jury is wrong, because—you know, I've tried lawsuits all my life, and you never say—you know, quote "juries are wrong." What I'm saying is, you don't submit that action to them. You can't have juries deciding what the—what the United States Public Health Service should do. I mean, you get into this interesting anomaly and I'd like you to consider it. If the 9th circuit—if—if you rule against us and say comment k doesn't apply, the instructions were okay, the verdict ought to stand as it is, where does that leave American Cyanamid? Where does it leave people who make vaccines, not just Cyanamid? What are we saying, in the 9th circuit we can't sell it, but we can sell it in the 10th circuit? You know, I think sometime you have to say that the feds have to control this type of vaccine, that you have to have professionals back there that say, we deem it—and you're talking about the American Pediatrics Society, the American Medical Association, the NRH, the CDC, everybody says, give this vaccine. What are we suppose to say now? You can't give it in Idaho?

JUSTICE HUNTLEY: Well, Mr. Koontz, you are in effect, I think on the bottom line here, virtually asking us to take this out of the jury system and defer to the FDA. Now . . .

MR. KOONTZ: No. No, I'm not asking . . .

JUSTICE HUNTELY: You're not . . .

MR. KOONTZ: No, and I think—and that's why I asked you to defer to the . . . PMA amicus brief, to say —this is how—this is the history of comment k that started, you know, way back when. They're not talking necessarily about FDA approval. What they're saying is, if medical science can't develop anything any better, we're not going to let a lay jury sit here with some expert who comes from Kuna, Idaho, saying, Hey I can build a better mouse trap and they should have built it. That's what we're saying. It's a warning issue, and it's an improper manufacture issue.

JUSTICE HUNTELY: Well, I'm genuinely trying to have this discussion with you to get the concepts clear in my mind as to what you're proposing and what the consequence of it is. I have to say that it seems to me where you've taken us is to the point of saying that in the case where there is at a present moment in history only one product on the market and it's unavoidably unsafe, we cannot have a jury question and should not submit to the jury and should not submit to the jury the question of whether it was negligent to have produced that drug even if a plaintiff can establish that there was a way to manufacture a better and safer drug.

MR. KOONTZ: I think that's—that's accurate given the limitations of comment k, that it was manufactured in accordance with FDA, NIH, CDC or whatever standard you want to talk about. But it was not a defectively manufactured product in the sense that it wasn't what it was suppose to be when it was manufactured, and that there was proper warning given. Because every case, and this is interesting, every case. Mr. Pederson criticizes me because all I cited was warning cases. I

look at his brief, all he cites are warning cases, because from Davis on, that's all you're talking about, are warning cases. You know, were the warnings proper to the learned intermediary. He's got to ultimately make the decision. Because I think you have to think, Justice Huntley, not in a sense just of this vaccine, but think about the new drugs that are coming out for—you know, for heart patients, the artificial heart. Are we now going to have a year from now somebody saying Debachy didn't do it right. . . .

JUSTICE HUNTLEY: Well, there—there's a problem that we've all had experience with. The testing on these new drugs is usually done by the proponents who wish to market them or their independent labs. And we know of case after case in history where the data they have submitted to the FDA was incorrect.

MR. KOONTZ: Oh, Judge—I mean, Justice Huntley, that's a separate exception in comment k, the fraud exception. I mean, if American Cyanamid produces a drug—if the DPT vaccine, if they had erroneous information, the FDA, I don't have any problem in saying that's a jury issue, back there. If they submitted erroneous information, the FDA stick 'em. I don't have any problem with that at all. I mean, those are questions where there was fraud involved, and I'm sure if fraud is not too strong a term, but I'll . . . accept what you said.

JUSTICE HUNTLEY: I didn't say fraud. I said inadequate testing . . .

MR. KOONTZ: Well you and I are talking about the same thing. You're talking about hoodwinking the government in terms of what happens with a drug that you want to license. Now, that's not the DPT vaccine, its' been licensed since 1944 or 45. Nobody has ever suggested, and it as not—Mr. Patterson will agree, in this case, nobody's ever suggested in this case that American (inaudible) would ever produce any evidence to the FDA or the NIH or the CDC, or anybody else, but Bu-

reau of Biologics that was inaccurate information. And I would agree with you that inaccurate information which you're getting into some of the—the recent cases of (inaudible) basically fraud with the government where the drug company lied to them. And I don't have any problem with—that's an exception to 402(a)(k) which is in there. It says we—we accept the fraud rule. That's —that has no part of this case, and I don't want you to get confused on that—that area.

[Appendix B to the Idaho Supreme Court Opinion]

Oral Argument of Malcolm E. Wheeler
for Pharmaceutical Manufacturers
Association

MR. WHEELER: May it please the Court. Your Honors, I'm here on behalf of the Pharmaceutical Manufacturers Association and as such I don't propose to get into the specific facts of this case and I think it probably will even help the Court's analysis, and certainly my own, if we don't get into a discussion or any bickering between me and the plaintiff's counsel over whether we are, in fact, trying to engraft comment k onto negligence. Because what I view as being the question that's before this Court today is, in fact, much more easily framed than to talk about comment k. It's a policy question. And the question is, does this Court, as the highest court in the state of Idaho, and the court that is ultimately responsible for articulating the common law of the jurisdiction, want to articulate a common law that allows a plaintiff to sue a pharmaceutical manufacturer when that plaintiff has, (1) voluntarily chosen to use a particular vaccine or a drug, as the case may be, having been fully warned of what the possible risks, what the possible consequences and side effects of that drug might be . . .
JUSTICE SHEPARD: Warned by who?

MR. WHEELER: . . . or in this case a vaccine. A learned intermediary, namely a doctor. And that's a persevering point, Your Honor. And, (3) where the plaintiff does not contend in any way, shape or form that the warnings were inadequate, that the product was improperly manufactured, that it failed to do what it was held out to do, or that it did something . . . (END OF TAPE) . . . common law policy to allow a plaintiff to sue on the ground that this manufacturer, having developed a drug or a vaccine in this case, that prevents illness and disease and suffering. Having done that, now it thereby incurs an obligation to do more research and

develop an alternative arguably safer or more efficacious product. That is really the issue. And I want to go directly, if I may, to Justice Huntley's question, because I will take that one head on. And Your Honor, the answer is, I think that what this Court ought to do, as a matter of common law policy, is to rule that a plaintiff ought not to be allowed, in fact, to bring an action in negligence or in strict liability in which the contention is that a product, a pharmaceutical product that is a prescription medicine that has in fact been certified or licensed by the FDA, cannot bring an action that says that manufacturer has an obligation to make a different product. The plaintiff can bring the following actions—can bring an action in which the plaintiff argues that the product was improperly made. That is to say, it was impure, there was something about the process by which it was made so that the person in fact incur an illness, a disease, or some harm that wasn't anticipated. That's a legitimate claim. Number two, a plaintiff ought to be able to sue on the ground that the manufacturer did not sufficiently test so as to be able to discover what side effects this drug might have. Number three, the plaintiff ought to be able to sue on the ground that the manufacturer had knowledge. They should have generated warnings of a different type than the warnings that were given. And finally, the plaintiff ought to be able to sue on the following ground, and I'm quoting directly from McDaniel v. McNeil Laboratories, which is a case cited by both sides. On page 828 of the McDaniel case, the Nebraska Supreme Court said, "The FDA's determination is persuasive and controlling in the absence of evidence that the determination was based upon inaccurate, incomplete, misleading or fraudulent information. And that goes directly to the question that you asked, Justice Huntley, which is, "If the information is incomplete because the manufacturer did inadequate testing, or its incomplete because the manufacturer withheld it, whether intentionally, or negligently or recklessly," a suit would be

proper. But what we cannot have, what makes no sense, as a matter of public policy, is to have a rule of law that says that someone who does a good deed, a manufacturer who develops a lifesaving, or illness preventing, or a disease preventing product, that by having done that and having put that product on the market and made it available to the public to prevent disease or cure illness, thereby incurs an obligation to use its earnings to generate a better product. That kind of a rule just doesn't make any sense and you can see what the ramifications of a rule like that have to be. What the ramifications have to be are (1) you will get some manufacturers—or forget manufacturers, you will get some scientists, some independent researchers, who having developed a new product will say to themselves, do I dare put this product on the market today? Do I dare apply for a license from the FDA? Because, even if it get the FDA license, some plaintiff can come down and say, "Well wait a minute. You should not have put that product out so fast, even though everybody agrees that its social utility outweighs its risks, because if you just waited a little longer and spent a little more money, you might have developed even a better product." So you'll have people who are going to refrain from putting a product on the market at a time when it could help people; (2) And this is not a threat, and it's not blackmail as plaintiff's counsel would have it. If you look at the examples that we've cited in our brief of the DPT vaccine history, of the polio vaccine history, of the measles and mumps vaccine history, you will see that it is empirically the case that when this kind of liability follows that what the manufacturers are forced to do—they have no choice, is withdraw from the market. Now that's not blackmail, that's empirical fact. So, what I ask the Court to do is to focus both in the conceptual underpinnings of what the plaintiff's claim is an on the empirical evidence. And what I would like to do now is to go through and explain, not so much in terms of comment k, or why comment k should apply to negligence claims. I'd like to just go

through and explain what the policy reasons are that, in fact, make the pharmaceutical industry, that is, prescription drugs as opposed to patent-type drugs. What makes them unique? Why do we need to treat them differently than we treat automobiles and why do we need to treat them differently than we treat drill presses and punch presses? Let me begin again by reference to Justice Huntley's question. "Is the result of this that manufacturers are going to be able to market negligently made products?" The answer to that is clearly, no. What it is is its a rule that says who should determine whether the manufacturer engaged in negligent conduct? Should that determination of negligence vel non be made by jury after jury, after jury, some in Idaho, some in Washington, some in California, some in Missouri, or, should it be made by the expert agency, in this case the FDA, that has the massive scientific knowledge and the expertise to be able to make that reasonable determination. Let me—let me in fact be very specific with an example. Someone mentioned the Pinto. The Pinto, of course, received a lot of adverse notoriety. But what very few people realize is that after the very famous Pinto case, which was the Grimshaw case, that Indiana criminal case occurred and the jury found for not guilty on the charge. Seven months later, Ford Motor Company tried another Pinto case in San Antonio, Texas, and the jury found there was no defect and no negligence. Now, was Ford negligent? Was the Pinto defective? You have a San Antonio jury that says no. You have a California jury that says yes. You have an Indiana jury that says no criminal liability. Well, I don't know what the answer is on the Pinto, but what I do know is that the answer with respect to a pharmaceutical prescription drug is one that has to be determined once and for all. You can't have a situation where you put out a life-saving, illness preventing, disease curing product and then subject the manufacturer of that product, when the agency has said that the—that the benefits outweigh the risks,

you can't subject that manufacturer over and over and over again to potential liability.

JUSTICE HUNTLEY: Counsel, I'm sure you're aware of the limitations of staff and the funding that the FDA has, like almost any other agency has. This suggestion that we should defer, take it away from the jury —well, for example to be—to give a gross example, thalidomide was approved by the same agent—the FDA-type agencies of both Germany and England. Isn't it a pretty astonishing thing you're asking us to take all this away from the jury system?

MR. WHEELER: I don't think—I think it's unusual, Your Honor. I don't think its astonishing. It's—there's no question. No one's going to stand up. I think even the FDA itself, and try to represent to this Court or any other forum that they're perfect, and that they're not going to make mistakes. thalidomide it's my recollection and also in the MER cases was that there was in fact the finding that information was withheld, that the information was incomplete. And I don't mean fraudulently, I mean either negligently or—or in some form. That would answer those questions. But I'm prepared to go beyond that, Your Honor. There are going to be cases, over the years, I don't know how many it will be. Maybe it will be one, maybe it will be five, some percentage of the time the FDA will make mistakes. But the fact is that juries make mistakes. Again, which jury was right in the Pinto case? Was the San Antonio jury right? Was the California jury right? Was Ford negligent or was it not? We don't really know. There's no—that's a—an imponderable, unanswerable question because you have two findings and you simply can't say what the answer is. It's going to be the case that some people within the FDA as to a particular application will say, we shouldn't approve that. And other people within the FDA undoubtedly, on some cases, are going to say, yes we should approve that. And there will be a difference of opinion. But at least in those instances the people making the judgment will have the benefit of years of

experience and of all the data that they're able to compel the manufacturers to produce. The jury doesn't have that. As the Court knows, in a typical negligence trial there are all the artificial constraints of hearsay, the limitations on who can testify and what they can say, and you get a very, very different kind of analysis. But the bottom line question that the FDA people are asking is the same bottom-line question, which is, does the benefit of this product outweigh the risk of this product? But they're in a much better position to make that determination. Let me make—let me give you a couple of other examples of why. In the typical negligence case, automobile, punch press, drill press, ladder, anything of that nature, what the jury is asked to do is to go through the typical Judge Learned Hand formula from U.S. v. Carroll Towing Co. where they simply asked the question in gross, what are the risks of this product? What are the benefits of this product compared to some alternative design, and does the marginal risk outweigh the marginal utility. That's—it's in gross. It's a fairly easy question, although its in abstract terms, for a jury to answer. That's not the way it's done in the drug area. Why is that? Because in the drug area, the question is going to be, you have some benefits accruing to group A. In the case of a vaccine, all of the people who are prevented from catching this disease, 50,000, 40,000 whatever the number might be, they get the benefit of having had Tri-immunol on the market. Some smaller number of people are going to suffer and suffer terribly as a result. Juries are going to have to ask the question, group A v. Group B. Efficacy with respect to group A v. harm in group B. That's a very difficult question. It's essentially a moral question. It's a legislative question. It's the kind of a question that juries ought not to be asked to answer. They're ill-equipped to do it, and it's really an unfair question for juries. But it is a fair question for the legislatures and regulatory bodies that are created by legislatures to be required to answer. I see I'm out of time. I have many other points, but I thank you for your attention.

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 84-3906

D.C. No. CV-80-1245

DAVID TONER, Guardian ad litem for KEVIN TONER, an infant child, and DAVID TONER and SUSAN TONER, husband and wife, individually,

Plaintiffs-Appellees,

vs.

LEDERLE LABORATORIES, a division of AMERICAN CYANAMID CO., a corporation,

Defendant-Appellant.

Appeal from the United States District Court
for the District of Idaho

[Filed Nov. 23, 1987]

ORDER

Before: WRIGHT, KENNEDY, and ANDERSON, Circuit Judges.

The panel as constituted in the above case has voted to deny the petition for rehearing. Judges Kennedy and

Anderson have voted to reject the suggestion for a rehearing en banc, and Judge Wright recommends rejection of the suggestion for rehearing en banc.

The full court has been advised of the suggestion for en banc hearing, and no judge of the court has requested a vote on the suggestion for rehearing en banc. Fed. R. App. P. 35(b).

The petition for rehearing is denied, and the suggestion for a rehearing en banc is rejected.

APPENDIX E

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 87-1578

TRACY ISABEL ABBOT,
Plaintiff-Appellant,

v.

AMERICAN CYANAMID CO.,
Defendant-Appellee.

On Appeal from the United States District Court
for the Eastern District of Virginia

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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Defendant-Appellee.

On Appeal from the United States District Court
for the Eastern District of Virginia

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

INTEREST OF THE UNITED STATES

The United States submits this *amicus curiae* brief on behalf of the Department of Health and Human Services (HHS), which maintains a longstanding national program to vaccinate all American children against pertussis, or "whooping cough." The purpose of this brief is to provide the Court with background information concerning the federal government's role in pertussis vaccination. The United States expresses no opinion on the question whether federal law preempts plaintiff's state tort remedies in this case.

INTRODUCTION

Federal public health authorities, including the Food and Drug Administration (FDA), the Centers for Disease Control (CDC), the National Institutes of Health (NIH), and other agencies, have, for almost forty years, promoted vaccination of the populace with diptheria-tetanus-pertussis (DTP) vaccines containing as one of their three components the so-called "whole cell' pertussis vaccine.[1] These agencies have supported use of this "whole cell" component because of its proven value for millions of children, even though they recognize that it may have serious adverse side effects for a small number of those vaccinated. These agencies are unaware of any other pertussis vaccine produced in the world today that has been adequately demonstrated to be both safer than and as effective as the "whole cell" vaccine licensed for sale by the FDA.

Pertussis is a serious disease which is most dangerous to its youngest victims. Before the introduction of the "whole cell" vaccine, pertussis disabled and killed thousands of children annually in the United States. After more than 40 years of widespread use of that vaccine in this country, the disease has been brought largely under control. Pertussis remains a leading cause of infant deaths, however, in some other parts of the world which lack such vaccination programs.[2] Moreover, the bacterium causing the disease persists even where the disease is under control, as in this country. This leads to the probability of epidemics whenever the use of the vaccine declines significantly. The responsible federal health

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[1] Such a three-component vaccine was first licensed by the predecessor to FDA's Office of Biologics Research and Review in 1949.

[2] See 50 Fed. Reg. 51040-42 (1985) (report of the Panel on Review of Bacterial Vaccines and Toxoids). This report, by a group of non-government medical experts appointed by FDA to review the safety, efficacy and labeling of all bacterial vaccines, contains a thorough discussion of the disease, the development of the "whole cell" vaccine, and the vaccine's safety and efficacy.

agencies have consistently recommended that all children, excepting those with specific medical contraindications, be inoculated.

In this case, plaintiff Tracy Isabel Abbot sued American Cyanamid Company, whose subsidiary, Lederle Laboratories, manufactures a "whole cell" pertussis vaccine. The plaintiff asserted that she suffered permanent brain damage as a result of being inoculated when she was five months old with Lederle's FDA-licensed DTP vaccine. The three-count complaint specifically alleged strict liability, breach of implied warranty of merchantability, and negligence. In response to the defendant's motion for summary judgment, the plaintiff made clear that her case was based on the contentions that Lederle's "whole cell" vaccine was defectively designed and that warnings accompanying the product were inadequate. Brief For Plaintiff-Appellant at 3-5.

The "whole cell" pertussis vaccine is made from whole killed cells of *Bordetella pertussis*, the bacterial agent that causes the disease. The vaccine contains substances which may be able to cause adverse reactions in vaccinees. The plaintiff here contended that Lederle could have and should have manufactured and sold a different type of pertussis vaccine less likely to cause adverse reactions. The district court granted summary judgment for the defendant on the ground that the plaintiff's tort claims against the manufacturer were preempted by the comprehensive and pervasive federal regulation of vaccines.[3]

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[3] With respect to the inadequate warning claim, the district court alternatively based its grant of summary judgment on the "learned intermediary doctrine" (*i.e.*, where a physician exercising individualized medical judgment is interposed between the manufacturer of a prescription drug and the patient, the manufacturer's duty to warn is satisfied by adequate warning to the physician). On the basis of deposition testimony by the physician who administered the Lederle vaccine to Tracy Abbot that he considered the warnings accompanying the product to be adequate, the court concluded as a matter of law that the defendant had met its duty to warn.

DISCUSSION

HHS supports the continuing manufacture and marketing of the "whole cell" vaccine because no alternative formulation has been adequately proven to be both safer than and as effective as the "whole cell" vaccine. HHS's support for continued production of this product is consistent with the vigorous recommendations of all sectors of the medical community, both public and private, which have carefully analyzed the dangers of the disease and the benefits and risks associated with the vaccine.

Experts still have not determined what part of the whole *B. pertussis* cell used in the "whole cell" vaccine provides immunity to the recipient. HHS, the governments of other nations, and numerous private firms like Lederle are all actively seeking a vaccine that provides all of the protection of the "whole cell" design without the attendant adverse clinical reactions. Until the time that HHS is convinced that such an alternative vaccine has been found, it will continue to advocate the use of "whole cell" vaccine as a vital part of our nation's public health policy.

1. *History and Epidemiology of Pertussis.*

Pertussis, or whooping cough, is a highly contagious disease caused by *Bordetella pertussis*, a bacterium. Human beings are the only natural hosts of *B. pertussis*, and infected individuals are the primary sources of disease in susceptible persons. Transmission occurs via droplets from the respiratory tract which are expelled into the air by infected individuals. Up to 90% of nonimmune household contacts acquire the disease. *Report of the Committee on Infectious Diseases*, American Academy of Pediatrics (1986) ("The Red Book"). Later stages of the disease are characterized by severe and paroxysmal coughing which ends in a prolonged, high-pitched crow (the whoop) that is occasionally accompanied by vomiting. Recovery may take many weeks or months. The disease is most dangerous to infants and

young children. During the years 1940-1948, the mean annual pertussis mortality rate for infants up to 12 months of age was 64 per 100,000 population, as compared with only 6.4 per 100,000 children ages 1 through 4, and 0.2 for children ages 5 through 14. Cherry, "The Epidemiology of Pertussis and Pertussis Immunization in the United Kingdom and the United States: A Comparative Study," *Current Problems in Pediatrics* (1983) ("Cherry"), p. 18. Complications of pertussis include brain diseases, convulsions, partial lung collapse, secondary infections such as pneumonia, and permanent developmental retardation. See generally Manclark & Cowell, "Pertussis" in Germanier (ed.), *Bacterial Vaccines* (1984) ("Manclark & Cowell"), pp. 69-106.

In 1934, when this country suffered its worst pertussis epidemic, there were 265,000 reported cases of pertussis and 7,500 related deaths. Hinman and Koplan, *Pertussis and Pertussis Vaccine: Reanalysis of Benefits, Risks, and Costs*, Journal of the American Medical Association ("JAMA") (June 15, 1984). By the early 1940s, pertussis was responsible for two and half times the number of deaths as all of the following diseases combined: measles, mumps, rubella, diptheria, polio, meningitis, chicken pox, and scarlet fever. While the use of pertussis vaccine has reduced the number of deaths attributable to pertussis to approximately 10 per year ("Recommendation of the Immunization Practices Advisory Committee (ACIP," *Morbidity and Mortality Weekly Report*, ("MMWR") U.S. Dept. of H.H.S., July 12, 1985), the potential for epidemics is still present. JAMA, p. 3113.

2. *Development of the Whole Cell Pertussis Vaccine.*

B. pertussis was identified as the cause of whooping cough in 1906 at the Brussels Pasteur Institute. The first vaccine against pertussis was licensed by the federal government in 1914. Work began on the development of the forerunners of the current "whole cell" vaccines in the 1920s. This research led to the development

of experimental vaccines and clinical trials in the 1930s. In the early 1940s, pertussis vaccination became widespread, and, in 1944, the Council on Pharmacy and Chemistry of the American Medical Association (AMA) accepted and endorsed pertussis vaccination. From 1943 to 1976 the country showed a 99% reduction in the reported cases of pertussis per 100,000 population, and an even more dramatic reduction in the number of deaths. Both the number of cases and deaths due to pertussis have remained constant since 1976. Cherry, pp. 11-12. CDC believes that, since 1980, 95 percent of all American children who have reached five years of age have received the complete course of immunization against pertussis.

In 1949, federal criteria governing the manufacturing process and potency testing of all batches of pertussis vaccine were developed. The same year the federal government licensed a combined product consisting of diphtheria and tetanus toxoids and "whole cell" pertussis vaccine and approved the product's labeling as well.[4] This type of product is the familiar diphtheria-tetanus-pertussis (DTP) vaccine produced by Lederle and two other licensed domestic commercial manufacturers today.

According to the best information available to the government, of the ten companies that have at any time obtained licenses to manufacture or distribute DTP vaccine in this country, only three, Lederle, Wyeth Laboratories, Inc., and Connaught, Inc., continue to produce the vaccine.[5] They were also the only manufacturers or dis-

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[4] This labeling has been revised and updated as experience with the vaccine has increased. FDA specifically approved the labeling (known as the "package insert") accompanying the Lederle product in this case, finding it both accurate and adequate.

[5] Lederle and Connaught market their DTP products. Wyeth no longer markets its DTP vaccine, we understand, but does manufacture the vaccine which is then distributed by Lederle. SCLAVO, an Italian pharmaceutical firm, is licensed to manufacture and sell "whole cell" DTP vaccine in the United States but is not presently distributing its vaccine in this country.

tributors in 1983, when Tracy Abbot received her inoculations. The pertussis vaccine used by all three firms, then and now, is of the "whole cell" type.[6]

It is well recognized that the "whole cell" pertussis vaccine is associated with rare, serious adverse reactions. However, clinical trials, 50 years of experience with the vaccine, and the great reduction in the number of reported cases of the disease and related deaths all demonstrate that, used properly, the "whole cell" pertussis vaccine is acceptably safe and very effective in controlling the disease. Manclark & Cowell, p. 84.[7]

The importance of inoculating children with "whole cell" vaccine is perhaps best demonstrated by reviewing what happened in the United Kingdom and Japan during the 1970s when the use of the vaccine declined. Because of public concern regarding the "whole cell" pertussis vaccine, the number of individuals immunized against pertussis in Britain dropped from 79 percent in 1973 to 31 percent in 1978. An epidemic of pertussis broke out between 1977 and 1980 that resulted in 102,500 cases of disease and 36 related deaths. In the winter of 1981-1982, approximately 1,400 cases of pertussis were reported each week to British public health officials. A

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[6] The Michigan and Massachusetts state health laboratories also have licenses from FDA to produce DTP vaccines for use in their respective states. Those vaccines also incorporate the "whole cell" pertussis component.

[7] In a very recent decision, an Ohio appellate court essentially agreed with this conclusion. *White* v. *Wyeth Laboratories*, Nos. 52108 and 52564, slip op. at 13 (Court of Appeals of Ohio, Eighth District, July 30, 1987). The *White* court held that Wyeth's DTP vaccine containing a "whole cell" pertussis component was an "unavoidably unsafe product" because it was "an apparently useful and desirable product, attended with a known but apparently reasonable risk." *Id.* The court concluded that "[p]ublic policy requires that the mere manufacture of the vaccine not be actionable on design defect grounds" and that the manufacturer was not liable for adverse reactions associated with the vaccine if adequate warnings of the risks were provided. *Id.*

total of 49,543 cases were reported during the first nine months of 1982 alone. Cherry, pp. 36-39 and MMWR (December 3, 1982), p. 629. The Japanese had a similar experience when the use of the "whole cell" vaccine declined from approximately 70 percent in the early 1970s to approximately 30 or 40 percent in 1975. By 1979, the Japanese reported an epidemic of 13,105 cases of pertussis and 41 deaths. Manclark & Cowell, p. 94, and U.S. Department of Health and Human Services, "Pertussis and Pertussis Vaccines in Japan", May 9, 1986. CDC estimates that, under current conditions, if the use of "whole cell" pertussis vaccine were halted in this country, there would be 353,000 additional cases of disease and 450 deaths per year. JAMA, p. 3112.

3. *Other Vaccines.*

It is the plaintiff's theory in this case that Lederle should be held liable because a design defect in the "whole cell" vaccine made it unreasonably dangerous. According to the plaintiff, two other types of vaccines are as effective as the "whole cell" vaccine and are safer in that they cause fewer adverse reactions. See Brief For Plaintiff-Appellant at 4 and n.4. The plaintiff argued that Lederle, instead of manufacturing a "whole cell" vaccine, should have developed, obtained FDA license approval for, and marketed in 1983 either an extracted cell or an acellular vaccine. *Id.* HHS is unconvinced that current evidence demonstrates that there are presently safer and equally effective alternatives to the "whole cell" vaccine.

(a) *Extracted Vaccines.* Eli Lilly and Company manufactured and marketed a DTP product called "Tri-Solgen" between 1962 and 1977 under an FDA-approved license. "Tri-Solgen" contained a pertussis vaccine component prepared from an extract of whole *B. pertussis* cells that was a complex mixture which differed from whole cells primarily by being soluble. The extracted pertussis component of "Tri-Solgen" passed the same

laboratory tests for freedom from toxicity and for potency required for "whole cell" vaccines. The extracted vaccine was considered effective based upon the fact that it met the laboratory requirements for potency. However, no controlled clinical efficacy trials were ever performed on this vaccine comparable to those performed on "whole cell" vaccine in the 1940s and 1950s.

Following the decision by Eli Lilly to cease manufacture of "Tri-Solgen", Wyeth Laboratories, Inc., which was then producing a "whole cell" vaccine, took an option from Eli Lilly to produce a "Tri-Solgen"-type extracted pertussis vaccine. After considerable research, Wyeth produced its own extracted vaccine in the late 1970s and, in 1982, submitted a license application to the FDA to manufacture and sell a DTP vaccine containing such a pertussis component. The license application included research information, production data, and two small clinical trials evaluating immunogenicity (*i.e.*, capacity to confer immunity), as measured by antibody responses in children, and safety, as measured by adverse reaction information from all subjects tested. While there appeared to be fewer local and mild systemic reactions to the extracted vaccine than with "whole cell" vaccine, there were two severe reactions during the clinical tests—one episode of collapse and one episode of cyanosis—in the group receiving the extracted vaccine.

Wyeth's data were reviewed by FDA and by a panel of consultants convened by FDA. Based on the observation of the two serious reactions in children receiving the extracted vaccine and the fact that Wyeth's extracted vaccine had less potency than "whole cell" vaccine, they concluded that additional data would be necessary before a license could be issued.[8] While technically the application

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[8] Because the performance characteristics of biological products depend on the manufacturer, the manufacturing process, the manufacturing facility, and other variables, vaccines made by different manufacturers are treated as separate products, even if they are of

has not been withdrawn, it has remained inactive and no license has been issued for Wyeth's extracted vaccine. In 1985, Eli Lilly voluntarily requested FDA to revoke its license to manufacture "Tri-Solgen," and the agency accordingly granted Lilly's request.

(b) *Acellular vaccines.* Acellular pertussis vaccines differ from earlier vaccines in that they contain less endotoxin (a toxic substance produced by the pertussis bacterium). While the acellular vaccines, which are marketed by Japanese firms, have been reported to be safer in some respects than the "whole cell" products, it is not clear whether they are as effective. Since 1981, the acellular vaccines have been used in the mass immunization program in Japan. Although the results with these vaccines are encouraging, additional clinical trials are in progress to demonstrate safety and efficacy. One of the clinical trials being watched with great interest is presently underway in Sweden. Changes made in the Swedish "whole cell" vaccine in the 1970s rendered that vaccine ineffective and its use was discontinued. As a result, Sweden has experienced a significant increase in the number of cases of pertussis in the years since 1974. The present clinical trial of two Japanese acellular vaccines was designed by Swedish public health officials in close consultation with their American counterparts at FDA, NIH, and CDC, and the trial is being primarily funded by HHS. Neither of the two vaccines currently being tested in Sweden is licensed for use in the United States, and only one is approved for use in Japan.

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the same design and for the same purpose. Therefore, Wyeth could not simply make and sell "Tri-Solgen"; rather, Wyeth had to obtain the manufacturing technology from Lilly and develop its own extracted pertussis vaccine. Wyeth's vaccine was then subject to FDA evaluation without regard to the existing approval of Lilly's similar extracted pertussis vaccine. Although the Wyeth vaccine was not approved, it is not possible to conclude that "Tri-Solgen" was "better" than the Wyeth vaccine because different tests were done on the two vaccines.

Some early information is now available concerning the Swedish clinical trial. The study was designed as a classical randomized, double-blind, placebo-controlled trial.[9] Sweden could be used as the location for this type of study for several reasons: there is a relatively high incidence of pertussis among Swedish children, the country's medical care system is advanced and equipped to handle the extensive follow-up and record keeping functions such a study requires, and the Swedish health authorities do not recommend immunization against pertussis. Thus, investigators could ethically withhold both a vaccine known to be effective and acceptably safe (the "whole cell" vaccine) and a potentially useful experimental vaccine (acellular vaccines), and give a placebo instead. By comparison, HHS believes that it would be extraordinarily difficult to conduct such a study in the United States because there are so few cases of pertussis that it would take a trial including approximately 200,000 children to show any differences in safety or efficacy between the "whole cell" and acellular vaccines.

A total of 3,800 children, who were between the ages of six and nine months at the time of their first dose of vaccine, participated in the study in Sweden. All of the children received two doses of vaccine (or a placebo) which were given two to three months apart. Two acellular vaccines were used in the study, both produced in Japan. The two vaccines differ in that one is composed of equal parts of two pertussis antigens, while the other contains only one of the antigens. The double component product is one of the approximately six different acellular vaccines that the Japanese government has approved

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[9] In other words, in this trial the study population was randomly divided into three groups that were then given either of the two vaccines or an inert substance known as a placebo. Neither the scientists conducting the study nor the subjects knew which individuals received the two vaccines or which received the placebo. In such a double-blind study, only once the trial is complete and scientists are ready to analyze its results do they "break the code" to determine the effects of the vaccine.

for use in its mass immunization program.[10] The single component vaccine is not, to the best of our knowledge, approved for general use in Japan at this time.

Data concerning adverse reactions which were reported in the children participating in the study, including the deaths of four of the children, are currently being evaluated. The deaths took place between two weeks and five months following the final injection of vaccine, and each was caused by or associated with a severe bacterial infection. Researchers broke the study codes, and it was determined that three of the children had received the two-component Japanese-approved vaccine. The fourth child was in the group that received the new single component product. Any deaths occurring in a study population this small are, of course, taken very seriously. Investigators do not yet know whether these deaths are related to the vaccines in any way and they are exploring that possibility.

The formal analysis of the data amassed in this study —the first controlled efficacy study on any of the new acellular pertussis vaccines—will begin in November, with the final report of the findings expected in mid-1988. The Japanese put their acellular vaccines into widespread use in the absence of a controlled study demonstrating that each of the vaccines was effective in preventing pertussis. Thus, the impact of these acellular vaccines on the incidence of the disease in Japan is difficult to evaluate according to some observers. The acellular vaccines appear to be associated with fewer mild local and systemic reactions than the "whole cell" vaccine, and few of the rare and very serious adverse events (such as that alleged by the plaintiff in this case) have been reported to the Japanese government's vaccine compensation system. "Acellular and Whole Cell Per-

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[10] Each of these vaccines is composed of different antigens in different ratios to each other. Each product is thus distinct and may have different safety and efficacy characteristics.

tussis Vaccines in Japan," *Journal of the American Medical Association* ("JAMA") March 13, 1987, 1351-56. Passive reporting systems, which rely on individuals to bring adverse reactions to the attention of public authorities, are not a reliable indicator of the real incidence of adverse reactions, however. The Swedish clinical trial is expected to provide the first scientifically solid proof of whether the acellular vaccines are actually effective in preventing the disease. This study is too small, however, to provide any information concerning rare serious adverse reactions. Thus, even once the Swedish study has been completed, it will take additional time to accumulate such safety data.[11]

The plaintiff argues that because there already existed two types of pertussis vaccine (extracted and acellular) that were as effective as and safer than the "whole cell" vaccine, Lederle could easily have developed one of the other types of vaccine and licensed it for sale. See Brief For Plaintiff-Appellant at 4 and n.4. As the discussion above demonstrates, the state of the scientific knowledge concerning the safety and efficacy of the new types of pertussis vaccines is by no means so clearly settled.

In sum, based on their evaluation of the available scientific and medical evidence, HHS's public health experts have concluded that alternative pertussis vaccines have not yet been adequately shown to be safe and effective for licensure in the United States.

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[11] In addition, significant technical problems must be resolved before an acellular pertussis vaccine can be licensed for use in this country. Indeed, the last day of an international symposium on the development of acellular vaccines sponsored by the Department of Health and Human Services last year was devoted to these issues. They include, among many others, the optimal size and number of doses of the accellular vaccine necessary to confer immunity, the relevance of the Japanese experience (where children are vaccinated at age two years) to the United States (where infants begin receiving pertussis immunization at age two months), and the design of laboratory tests for the vaccine that will demonstrate clinical effectiveness.

4. *The Federal Role.*

In addition to FDA's role in the licensing and control testing of pertussis vaccines and in the conduct of research concerning the disease, the federal government is actively involved in soliciting and disseminating the views of outside experts on immunization policy, in directly administering federal immunization programs and assisting state programs throughout the country, and in purchasing substantial quantities of vaccine to create a federal stockpile for emergency use.

In the 1960s, the Public Health Service formed the Advisory Committee on Immunization Practices (ACIP), a body of medical specialists which is a prime source of expertise on vaccine issues. Periodically, the ACIP convenes to review vaccines and immunization practices and to make recommendations to public and private health care deliverers. Since its inception, the ACIP has consistently recommended the use of the currently-licensed "whole cell" pertussis vaccine. MMWR, July 12, 1985, p. 2. In reaching its recommendations, the ACIP reviewed the available data concerning the risks of the disease and the pertussis vaccine. The ACIP determined that the risks of rare, severe adverse reactions, including permanent brain damage, temporally associated with the administration of the vaccine were outweighed by the severe clinical course of the disease (for example, well over half of the infants with pertussis have required hospitalization), the seriousness of the possible complications and permanent consequences, and the infant fatality rate. *Id.* Specifically aware of the possibility of rare, serious adverse reactions associated with the "whole cell" vaccine, the ACIP has concluded, nonetheless, that vaccination against pertussis with this vaccine early in life is essential. The American Academy of Pediatrics, through its Committee on Infectious Diseases, also officially supports this conclusion regarding the importance of immunization with the "whole cell" pertussis vaccine. The Red Book, p. 266-275.

The ACIP has identified certain children who should not receive pertussis vaccine for specific medical reasons and has identified possible adverse reactions and symptoms that contraindicate further immunization with the pertussis vaccine. MMWR, July 12, 1985, p. 7. Lederle's physician labeling includes all warnings recommended by the ACIP.

The ACIP's recommendations appear in the *Morbidity and Mortality Weekly Report* (MMWR), the major information publication of the CDC, which is widely distributed to state and local public health officials and to physicians in private practice and academia. In addition to the publication of the ACIP's views, CDC provides technical assistance concerning immunization, including pertussis immunization, to state and local health departments through a network of regional medical epidemiologists and public health advisors. These CDC representatives are assigned to each state and to some major metropolitan areas, and they participate in their respective states' immunization programs by providing educational information, clarifying the ACIP's recommendations, and helping to ensure an adequate supply of vaccines.

CDC is also a major purchaser of DTP vaccine. In order to achieve the maximum economies of scale and thereby minimize the impact of significant recent increases in the price of the vaccine, CDC last year made a consolidated federal purchase of the vaccine for use by state public health programs.[12] This vaccine is then available at a reduced price to the state health departments for distribution in local public health clinics. The

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[12] The CDC makes its decision from who to purchase its DTP supply solely on the basis of cost, since CDC is convinced that the three licensed manufacturers of DTP vaccine in this country produce equally acceptable, safe, and effective products. During the 12-month period ending in April 1987, CDC purchased nine million doses of the vaccine as part of this program.

funds for this purchase are authorized under the Immunization Grant Program, formerly known as the Vaccination Assistance Act of 1962, 42 U.S.C. § 247b.[13] The CDC has developed an "Important Information Statement", based on the ACIP recommendations, which discusses the risks and benefits of the "whole cell" vaccine and which must be provided to vaccinees and/or their parents before any vaccine purchased through the federal progam is administered. This statement is made freely available to state officials by CDC, and state officials then distribute the statement to their clinics and to private physicians on request. It is believed that the statement is used by many physicians in private practice to inform parents of the benefits and risks associated with immunization with the pertussis vaccine.

In addition to the consolidated federal purchase, the CDC has ordered large quantities of the vaccine in an effort to build a federal stockpile that would represent approximately a six months' supply (four million doses). The stockpiling efforts were undertaken in response to a shortage in the supply of the vaccine that occurred in 1984 when there were vaccine production problems and when two of the three licensed manufacturers stopped selling the vaccine for about six months (reportedly due to the manufacturers' inability to arrange for acceptable liability insurance coverage). The supply of DTP in 1983, which was adequate to meet the country's need, was approximately 18.2 million doses, which decreased to 15.6 million in 1984. As a result of the shortage, it was necessary for the ACIP to recommend a change in the immunization schedule, postponing the final two doses of the series of five needed for complete protection. The vaccine shortage recently experienced was a serious public health concern but its impact would appear mild in

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[13] Virginia receives grants under this program and is served by a CDC representative in the state who coordinates state and local programs.

comparison with the effects of a larger and longer-lasting shortage.[14]

While the government supports the current use of the "whole cell" vaccine, various federal public health agencies are actively involved in pertussis-related research aimed at developing new types of vaccines which may be associated with fewer severe reactions. Government agencies such as NIH, CDC, and FDA are conducting studies in their own laboratories on various aspects of the disease and on new vaccines. These agencies also support research on pertussis in the private sector through grants and contracts.

The possibility that a vitally important vaccine may be denied to the public before a better alternative becomes available remains of great significance to the public health community. This concern is heightened when the current vaccine has been licensed by the FDA and when its use is strongly recommended by the Public Health Service.

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[14] The CDC reports that in 1986 there was another shortage of DTP vaccine in the United States. This shortfall was not as serious as that experienced in 1984, but in order to insure that all state and local health departments had an adequate amount of the vaccine, the CDC distributed between 800,000 to 900,000 doses of the one million doses of DTP then in its stockpile. Because of this shortfall and because the manufacturers are producing the vaccine at the limit of their current capacity, it will take longer than expected to accumulate an adequate federal stockpile of the vaccine. In the opinion of the responsible agencies of the U.S. Public Health Service, the regular supply of DTP vaccine has been marginal at best for the last ten years, and a federal stockpile is therefore viewed as extremely important.

CONCLUSION

The United States presents the foregoing information to this Court.

Respectfully submitted,

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AUGUST 1987

CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of August, 1987, I served the foregoing Brief For The United States as Amicus Curiae upon counsel by causing copies to be mailed, postage prepaid to:

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APPENDIX F

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO

Case No. 80-1245

DAVID TONER, Guardian ad litem for KEVIN TONER, an infant child, and DAVID TONER and SUSAN TONER, husband and wife, individually,

Plaintiffs,

vs.

LEDERLE LABORATORIES, a division of AMERICAN CYANAMID COMPANY, a corporation,

Defendant.

[Filed June 20, 1984]

JURY INSTRUCTIONS
BEFORE THE HONORABLE RAY McNICHOLS
APRIL 23, 1984

APPEARANCES:

Plaintiffs—

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* * * *

INSTRUCTION NO. 20: Under their claim, the first claim, that the product was defective, the plaintiffs have the burden of proving each of the following:

1. That the defendant was a merchant with respect to the product involved in the lawsuit; that is not really disputed.

2. That the product was in a defective condition and unreasonably dangerous to persons when it left the hands of the defendant;

3. That the unreasonably dangerous defective condition in the product was the proximate cause of injuries to the plaintiff Kevin Toner; and

4. The nature and extent of the injuries, and the amount thereof.

INSTRUCTION NO. 21: A product is in a defective condition, unreasonably dangerous to persons if it is more dangerous than would be expected by an ordinary person who may reasonably be expected to use it. The law does not say what would be expected by an ordinary person or who may reasonably be expected to use the product. Both of these issues are for you to decide.

INSTRUCTION NO. 22: A manufacturer of a product includes any person who designs, manufactures or remanufactures that product or any component parts before its sale to a consumer (and any person who otherwise holds himself out as a manufacturer). A person designs a product if he prepares or provides the design for that product.

INSTRUCTION NO. 23: Now, going to the second claim of the plaintiffs, the plaintiffs have the burden of proving each of the following propositions in order to prove their claim of negligence:

1. That the defendant acted, or failed to act, in one of the ways claimed by the plaintiffs, and that in so acting, or failing to act, the defendant was negligent.

2. That the plaintiff Kevin Toner was injured.

3. That the negligence of the defendant was the proximate cause of said injuries.

4. The nature and extent of the injuries, the elements of damages, and the amount thereof.

If you find from your consideration of all the evidence that all of the propositions required of the plaintiffs have been proved, then you should find for the plaintiffs on the negligence case. If you find from your consideration of all the evidence that any one of the propositions the plaintiffs are required to prove has not been proved, then your verdict should be for the defendant on the plaintiffs' negligence case.

INSTRUCTION NO. 24: When I use the word "negligence" in these Instructions, I mean the failure to use ordinary care in the management of one's property or person. The words "ordinary care" mean the care a reasonably careful person would use under circumstances similar to those shown by the evidence. Negligence may thus consist of the failure to do something which a reasonably careful person would not do, under circumstances similar to those shown by the evidence. The law does not say how a reasonably careful person would act under those circumstances. That is for you to decide.

INSTRUCTION NO. 25: When I use the expression "proximate cause", I mean a cause which, in natural or probable sequence, produced the damage complained of.

INSTRUCTION NO. 26: The manufacturer of a product is negligent if he does not use ordinary care in the design or manufacture of that product to avoid an unreasonable risk of foreseeable injury to a person using the product with ordinary care.

INSTRUCTION NO. 27: A manufacturer of vaccines has the duty to exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products. The

failure to meet this standard of due care in light of all the attendant circumstances will constitute negligence and subject the manufacturer to liability for the resulting consequences. The fact that the consumer's injuries were proximately caused by the manufacturer's product does not in and of itself constitute a sufficient basis upon which to predicate the manufacturer's liability. When the cause of action sounds in negligence, a manufacturer's duty to additionally test and investigate the propensities of its product is dependent upon the foreseeable risk of harm to potential users in light of then current scientific or medical knowledge and discoveries.

INSTRUCTION NO. 28: Now, under the third contention of the plaintiffs, under the theory of implied warranty of merchantibility, the plaintiff has the burden of proving each of the following:

1. That defendant was a merchant with respect to goods of the same type as the product involved in this lawsuit; not a fact in serious dispute;

2. That defendant sold the product involved in this lawsuit to the plaintiff; agreed fact,

3. A breach of the implied warranty of merchantibility;

4. That the plaintiff notified the defendant of the breach within a reasonable time after the plaintiff discovered, or should have discovered it;

5. That the breach was the proximate cause of injuries to the plaintiff; and

6. The nature and extent of the damages and the amount thereof.

INSTRUCTION NO. 29: An implied warranty of merchantability arises whenever the seller of a product is a merchant with respect to goods of that type. A breach of this warranty occurs when the product is not fit for the ordinary purposes for which the product is to be used.

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